PB81-207722

# Pesticide Registration Standard - Deet

(U.S.) Environmental Protection Agency
Washington, DC

Dec 80

**U.S. Department of Commerce**
National Technical Information Service
**NTIS**

**REPORT DOCUMENTATION PAGE**

1. REPORT NO. EPA 540/RS-81-004

2.

PB81-207722

4. Title and Subtitle

Pesticide Registration Standard - Deet©

5. Report Date December 1980

6.

7. Author(s) U.S. Environmental Protection Agency - Registration Division (RD) and Special Pesticide Review Division (SPRD)

8. Performing Organization Rept. No.

9. Performing Organization Name and Address

U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.

(C)

(G)

12. Sponsoring Organization Name and Address

Same as #9

13. Type of Report & Period Covered

Final

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document presents the registration standard for Deet© and summarizes the requirements for registering or re-registering a pesticide containing that active ingredient. Requirements for submitting scientific data and evaluating hazards associated with the chemical are covered. The document also contains a bibliography citing all the studies reviewed by EPA in arriving at the positions and conclusions stated in the standard.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

Pesticides (Registration)
Deet©
Registration Standards
Re-registration process

c. COSATI Field/Group

18. Availability Statement

19. Security Class (This Report)

20. Security Class (This Page)

21. No. of Pages

22. Price

ANSI—Z39.18)

PRODUCT OF:
NATIONAL TECHNICAL INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

OPTIONAL FORM 272 (4-7
(Formerly NTIS-35)
Department of Commerce

# DEET

## Pesticide Registration Standard

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December 1980

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# I. HOW TO REGISTER UNDER A REGISTRATION STANDARD

Organization of the Standard
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Requirement to Re-register Under the Standard
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Data Compensation Requirements under FIFRA 3(c)(1)(D)
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## Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

## Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this Act;
(C) it will perform its intended function without unreasonable adverse effect on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a 'product-by-product' basis, evaluating each product-specific application independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the 'product-by-product' approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments. Second, over the years, as a result of continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 10, 1978 and 43 FR 37336, August 2, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the 'product-by-product' approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or re-registration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use", or "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide usually requires that an applicator be certified by the state or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions.A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with state or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the Chapter 2.

## Requirement to Re-register Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to re-register all currently registered products as expeditiously as possible. Congress also agreed that re-registration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for re-registration. Each application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for re-registration set forth in the Guidance Package which accompanies this Standard.

## "Product-Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29696, July 10, 1978, and 43 FR 37336, August 2, 1978), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular compositionor use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories (see the second chapter). The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that is "product-specific," i.e., data that relates only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

(B) "generic" data that pertains to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product-specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or re-registration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product-specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluation, with a single set of tests, of all products in the group, the Standard so indicates.) "Product-specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert," ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing the ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he re-registers his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

## Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(C)(1)(D), an applicant for registration, re-registration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which is described by the following criteria:

(1) the data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;
(2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for re-registration, or to support or maintain in effect an existing registration;
(3) the data are relevant to the Agency's decision to register or re-register the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);
(4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and

(5) the data are not those for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants who propose to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product.)

An applicant for re-registration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements showing his compliance with FIFRA Section 3(C)(1)(D).

An applicant would never be required to offer to pay for "product-specific" data submitted by another firm. In most cases, data which are specific to another firm's product will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the compositions of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product. If he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for the data.

Each applicant for registration or re-registration of a manufacturing-use or end-use product who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for re-registration (or new registration) under this Standard is found in the Guidance Package for this Standard.

Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate) and have not been located in the literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit these data to EPA. EPA must allow a reasonable period of time for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a Section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists the "generic" data gaps and notes the classes of products to which these data gaps pertain in its summary second chapter. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product-specific" data.

As part of the process of re-registering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps — whether the data in question is "product-specific" or "generic" — in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product-specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

## Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, copies of which are available for inspection at EPA in Washington, D.C., and may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in Chapter 2.

# II. REGULATORY POSITION

## A. Introduction

This chapter is the central part of the Registration Standard. It presents the Agency's regulatory position based on an evaluation of all registered products containing Deet as the sole active ingredient. After briefly discussing background information on the regulatory history, uses and production of Deet, this chapter explains the Agency's major concerns about the toxicology of Deet, the regulatory actions which will be pursued, and the criteria by which applications for registration of Deet products will be approved. Thus, this chapter contains all of the Agency's requirements or continued registration of Deet products and new product registrations that are covered by the Standard. Detailed analyses of the data upon which this regulatory position is based are presented in each of the disciplinary chapters, III through VII.

## B. Background

"Deet" is the common name for N,N-diethyl-m-toluamide, a multi-purpose insect repellent registered for direct application to human skin, clothing, household pets, tents and bedrolls and screens. Deet is a rather unique pesticide, because it is applied directly to the human body for purposes of repelling insects. It was developed and patented by the U.S. Army in 1946 for use by military personnel in insect-infested areas. Because Deet was recognized as one of the few products effective against mosquitoes and biting flies, it was registered for "domestic use" (use by the general public in the U.S.) in 1957. Subsequently, all Deet-containing products have been registered without any restrictions as to the amount or frequency of application to the body.

Deet products currently available to the public are marketed in a variety of liquids, foams, lotions, sprays, and impregnated materials. Formulations registered for direct application to human skin contain from 11.27% to 99.9% Deet as the active ingredient.

## C. Regulatory Decision

A review of the very limited data available as of October 24, 1980 indicates that the criteria for unreasonable adverse effects have not been met for products containing Deet (40 CFR 162.11(a)). However, the data do suggest that more complete testing must be required to satisfy specific health effects concerns revealed during the review of Deet.

First, the Deet data base is very incomplete, particularly in the area of chronic effects studies. Further, the available chronic toxicity data were inadequate to assess the long-term effects of Deet, i.e. oncogenicity, teratology, reproduction and mutagenicity. Several supplementary studies (dominant lethal mutagenicity, oral teratology, subchronic inhalation) indicate possible reproductive toxicity. Although the data are only suggestive it is imperative to conduct the necessary studies to resolve the possibility of adverse effects.

A second major concern is that because Deet is applied directly to the human body, an individual's exposure can be very high, especially when applications are repeated daily or even more frequently over a period of time. The available data indicate that about 38% of the population uses an insect repellent. Of this group, many use Deet only occasionally. However, some people apply large doses daily (up to 117.0 mg/kg/day) and repeatedly throughout part of the year. Exposures are even higher for those involved in outdoor work including military personnel (10.7 mg/kg/day up to 60 times per year.)

This profile of widespread and often repeated use creates a high potential for unreasonable adverse effects, especially considering the absence of many chronic studies and considering the questions raised above by existing studies.

Of additional concern is that several acute eye irritation studies demonstrate that certain Deet products are severe eye irritants. Eye irritation studies using technical grade (99.9%) Deet demonstrate that it produces temporary corneal opacity (clouding of the eye) in rabbits. Based on these results, the Agency determines that products containing 99.9% Deet are not registerable for domestic use (see 40 CFR 162.11 (c)(2)(i)(A)). Because the Agency has no eye irritation studies for products containing from 30% to 99.9% Deet, these data must be provided as soon as possible to determine if public health risks exist from use of these products.

Further, an Agency review of Deet confidential Statements of Formula shows that many registrants have not submitted revised Statements demonstrating that Freon propellants have been removed. The Agency reminds registrants that Freons have been banned for use in Deet pressurized liquids because they cause a depletion of the ozone layer (43 FR 11318). Products containing Freons are therefore not registerable under this Standard.

Finally, toxicologic concerns have emerged as to the health effects of pesticides in children. These concerns justify the need to study the dermal absorption rate of Deet in laboratory animals to determine if there is greater absorption through the skin of children than adults.

Based on all these concerns, the Agency has concluded that the following regulatory actions must be initiated immediately:

1. All basic chronic and acute toxicology data for technical and formulated Deet, as well as additional special studies must be submitted. These studies are listed in Tables 1 and 2; protocols for the special studies are available from the Agency. They must be submitted according to the stringent, accelerated schedule shown in the tables.

2. The Agency will prohibit registration or continued registration formulated Deet product which demonstrates acute eye irritation effects of corneal opacity, or eye irritation persisting for 7 days. These products currently include formulations containing 99.9% Deet. The Agency will not change or reduce the requirements for eye irritation testing of Deet, because of its intended use directly on human skin.

3. Deet products are registerable only if all of the terms and conditions of this Standard are met. These conditions are presented in the remainder of this chapter. Products not brought into compliance with the requirements of this Standard will be subject to suspension and/or cancellation. New products registered under this Standard are subject to the same conditions.

4. This Standard will be effective immediately. It will be appropriately revised after all required data have been reviewed and evaluated by the Agency. The Standard may be amended to add certain new uses and formulations not currently registered.

## D. Terms and Conditions of Registration

Applicants for registration or continued registration of Deet products subject to this Standard must comply with all terms and conditions described in this Standard, including commitment to fill data gaps according to the schedule specified in Tables 1 and 2. When applicable (see Chapter 1), applicants must offer to pay compensation to the extent required by Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act [FIFRA] as amended, 7 U.S.C. 136 (c)(1)(D) and 136 (c)(2)(D). The following registrants have submitted data in support of Deet registrations, and have not waived their rights to compensation for these data: Cutter Laboratories; Rhone-Poulenc Co.; Charles Pfizer and Company, Inc.; McLaughlin Gormley King Co.; S.C. Johnson and Sons, Inc.; Straight Arrow Co and; Tillar Enterprises.

Following is a summary of the terms and conditions of this standard, including the areas of product composition, acute toxicity, use sites, data requirements and labeling.

### Product Composition Standard

#### a. Technical Deet

To be registered under this Standard, technical Deet must comply with the product composition standard developed in the Product Chemistry chapter. Technical Deet must therefore contain a minimum of 95% active ingredient, with appropriate certification of upper limits of unintentional ingredients as defined in Chapter 3.

#### b. Formulated Deet

The following types of formulated Deet, with less than 95% active ingredient, and acceptable acute toxicity ratings are acceptable under this Standard:

Ready-to-Use Solution
Pressurized Liquid
Impregnated Material

Applicants for registration of these types of formulations must certify upper limits of impurities as described in Chapter 3, as well as upper and lower limits of inert ingredients.

The Agency finds the inert ingredient, Freon, indentified through a review of Confidential Statements of Formula, unacceptable for use in Deet formulations because of the potential to cause depletion of the ozone layer of the atmosphere (43 FR 11318).

## Acute Toxicity Limits

### 1. Technical Deet

Because technical Deet products are only for manufacturing use, there are no established acute toxi city limits for technical Deet.

### 2. Formulated Deet

To be registered for domestic use under this Standard, in accordance with FIFRA Section 3(d)(1)(C)(i), formulated (see Table 24 ) Deet products must have ratings no higher than Toxicity Category III or IV for each of the following acute effects:

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Dermal Irritation

Additionally, formulated Deet products must not demonstrate eye irritation persisting for seven days or any corneal opacity in test animals.

## Use Patterns

### 1. Technical Deet

To be registered under this Standard, technical Deet products may be repackaged or formulated only into end-use, insect repellents for domestic use.

### 2. Formulated Deet

To be registered under this Standard, formulated Deet products shall be labelled for use only as insect repellents for application to human skin, household pets, clothing, bedding, tents, and screens. Application to food or livestock shall be prohibited by label direction.

## Data Requirements

Applicants for registration of technical or formulated Deet products must cite or submit the data listed in Tables 1 and 2, respectively, by specified due dates. Data in this Standard that satisfy registration requirements may be cited, if the applicant establishes that the proposed product is substantially similar (as determined by percentage of active and inert ingredients, manufacturing impurities and different uses) to another product for which the Agency has received acceptable data. If data in this Standard are cited, compensation must first be offered to the submitter(s) of the data as explained in Chapter 1. The Agency will examine both active and inert ingredients to determine if products are similar. In front of each requirement in Tables 1

## PRODUCT-SPECIFIC DATA REQUIREMENTS FOR TECHNICAL PRODUCTS

### Product-Chemistry

Table 1

| Guideline Citation | Name of Test | Composition Characteristics | Does EPA Have Data To Satisfy This Requirement ? | Biblio-graphic Citation | Must Data Be Submitted Under FIFRA 3(c)(2)(B) ? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| 163.61-3 | Product identity and disclosure of ingredients | Minimum 95% active ingredient | No | - | Yes | 6 months |
| -4 | Description of manufacturing process | * | Yes-incomplete | Pfizer, Inc., 1976 MRID #00001036;<br>Bogard, T., 1976 MRID #GS0002014 | Yes | 24 months |
| -5 | Discussion on formation of unintentional ingredients | * | No | - | Yes | 24 months |
| -6 | Declaration and certification of ingredients limits | * | No | - | Yes | 6(24mos.*) |
| -7 | Product analytical methods and data | * | No | - | Yes | 6 months |
| 163.61-8(1) | Color | * | Yes | Hercules Powder Co, 1957 MRID #00001025 | No | - |
| -8(2) | Odor | * | Yes | S.C. Johnson & Son, Inc., 1977 MRID #00001100 | No | - |
| -8(4) | Solubility | * | No | - | - | 6 months |
| -8(5) | Stability | * | Yes | S.C. Johnson & Son, Inc., 1977 MRID #00001100 | No | - |
| -8(6) | Octanol/Water partition coefficient | * | No | - | Yes | 6 |
| -8(7) | Physical State | * | Yes | Hercules Inc., 1977 MRID # 00001068 | No | - |

* Any impurities at 0.1% or less-Information need not be submitted until 24 mos.

and 2 is listed the section of the Proposed Guidelines (43 FR 29696, July 10, 1978; and 43 FR 37336, August 22, 1978) which describe that type of data and when it is required. Applicants must submit, solely or through joint agreement, all information in the tables identified as data gaps.

Applicants will not be required to submit residue chemistry data because Deet has no food uses and is not expected to occur indirectly as a food residue.

## Required Labeling

All technical and formulated Deet products must bear appropriate labeling as specified in the Guidance Package which accompanies this Standard.

### 1. Technical Deet

All technical Deet products must list on the label the intended end-use of formulated products produced from the technical products. Therefore, in addition to basic labeling, all technical Deet product labels must bear the following statement:

"For Formulation into End-Use Insect Repellent Products Intended Only for Domestic, Nonfood Use."

### 2. Formulated Deet

In addition to the basic labeling requirements, to reduce the possibility of inadvertent application to food and livestock, all formulated Deet products must bear the following statement:

"Do Not Apply Near Food or to Livestock"

All formulated Deet products must bear an appropriate statement of practical first-aid treatment in case of accidental ingestion or eye contact.

For formulated Deet products which present label claims that the product is effective against insects which might affect public health, the Agency will require registrants to submit data to support these claims. All labels which claim that Deet repels the following pests, must be supported by company data or published literature:

biting flies (black fly, sandfly, horsefly and Ceratopogonid species only)
chiggers
deerflies
fleas
leaches
mosquitoes
stableflies
ticks

Data required by the Agency in support of Deet's efficacy are listed in Table 3. These data are explained in detail in Chapter VII.

## PRODUCT-SPECIFIC DATA REQUIREMENTS FOR TECHNICAL PRODUCTS

### Product Chemistry

Table 1 Cont'd

| Guideline Citation | Name of Test | Composition Characteristics | Does EPA Have Data To Satisfy This Requirement ? | Bibliographic Citation | Must Data Be Submitted Under FIFRA 3(c)(2)(B) ? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| -8(8) | Specific gravity | Minimum 95% active ingredient | Yes | Hercules Inc., 1977 MRID # 00001000 | No | - |
| -8(9) | Boiling point | " | Yes | S.C. Johnson & Son, Inc., 1977 MRID #00001100 | No | - |
| -8(10) | Vapor pressure | " | Yes | Blaine *et al*., 1974 MRID # 05002553 | No | |
| -8(11) | pH | " | No | - | Yes | 6 months |
| -8(12) | Storage stability | " | No | - | Yes | 6 months |
| -8(13) | Flammability | " | Yes | S.C. Johnson & Son, Inc., 1977 MRID # 00001100<br>Hercules, Inc., 1972 MRID #00001152 | No | - |
| -8(14) | Oxidizing or reducing action | " | No | - | Yes | 6 months |
| -8(15) | Explosiveness | " | No | - | Yes | 6 months |
| -8(17) | Viscosity coefficient | " | Yes | S.C. Johnson & Son, Inc., 1977 MRID #00001100<br>Hercules, Inc., 1972 MRID # 00001152 | No | - |
| -8(18) | Corrosion characteristics | " | Yes | Hercules Powder Co., 1957 MRID # 00001025 | No | - |

## GENERIC DATA REQUIREMENTS FOR TECHNICAL PRODUCTS

### Environmental Fate

Table 1 cont'd.

| Guidelines Citation | Name of Test | Composition | Does EPA Have Data To Satisfy This Requirement? | Bibliographic Citation | Must Data Be Submitted Under FIFRA 3(c)(2)(B)? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| 163.62-7(c) | Hydrolysis | Minimum 95% active ingredient | No | - | Yes | 6 months |
| 163.62-8(g) | Activated sludge metabolism | * | No | - | Yes | 6 months |
| See Chapter 4 | Human use and exposure data | * | No | - | Yes | 12 months |

## GENERIC DATA REQUIREMENTS FOR TECHNICAL PRODUCTS

## Toxicology

Table 1 Cont'd

| Guideline Citation | Name of Test | Composition Characteristics | Does EPA Have Data to Satisfy This Requirement ? | Bibliographic Citations | Must Data Be Submitted Under FIFRA 3 (c) (2) (B)? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| 163.82-3 | Subchronic 90-Day Dermal Toxicity | Minimum 95% Active Ingredient | No | - | Yes | 12 months |
| 163.82-4 | Subchronic Inhalation Toxicity | " | Yes | U.S. Army, 1980<br>MRID # GS0002032 | No | - |
| 163.83-1 | Chronic Dermal Toxicity | " | No | - | Yes | 4 1/2 years |
| 163.83-2 | Dermal Oncogenicity (Mouse) | " | No | - | Yes | 4 1/2 years |
| 163.83-3 | Dermal Teratogenicity (Rat) | " | No | - | Yes | 1 year |
| 163.83-4 | Dermal Reproduction (Rat) | " | No | - | Yes | 3 1/2 years |
| 163.84-2 through -4 | Mutagenicity | " | No | - | Yes | 12 months |
| 163.85-1 | Metabolism (Identification of Metabolites) | " | No | - | Yes | 18 months |
| Protocols will be furnished by the Agency | Age-Related Dermal Absorption Studies (Rats) | " | No (Special Testing) | - | Yes | 18 months |

## GENERIC DATA REQUIREMENTS FOR TECHNICAL PRODUCTS

### Toxicology

Table 1 Cont'd

| Guideline Citation | Name of Test | Composition Characteristics | Does EPA Have Data to Satisfy This Requirement ? | Bibliographic Citations | Must Data Be Submitted Under FIFRA 3 (c) (2) (B)? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| 163.81-1 | Acute Oral Toxicity | Minimum 95% Active Ingredient | Yes | See Table 8 | No | - |
| 163.81-2 | Acute Dermal Toxicity | " | Yes | See Table 11 | No | - |
| 163.81-3 | Acute Inhalation Toxicity | " | Yes | U,S. Army 1979<br>MRID #GS0002034 | No | - |
| 163.81-4 | Primary Eye Irritation | " | Yes | U.S. Army 1979<br>MRID #GS0002025 | No | - |
| 163.81-5 | Primary Dermal Irritation | " | Yes | See Table 15 | No | - |
| 163.81-6 | Dermal Sensitization | " | Yes | U.S. Army 1979<br>MRID #GS0002026 | No | - |

GENERIC DATA REQUIREMENTS FOR TECHNICAL PRODUCTS

Ecological Effects

Table 1 Cont'd

| Guideline Citation | Name of Test | Composition | Does EPA Have Data to Satisfy this Requirement? | Bibliographic Citation | Must Data Be Submitted Under FIFRA 3(c)(2)(B) | Months Allowed Before Submission |
|---|---|---|---|---|---|---|
| 163.71-1 | Avian single-dose oral LD 50 (wild waterfowl, preferably mallard duck) | Minimum 95% active ingredient | No | - | Yes | 6 months |
| 163.72-1 | Fish acute LC 50 (coldwater species) | " | Yes | McCann, J.A. (1972) MRID # 00001026 | No | 6 months |
| 163.72-1 | Fish acute LC 50 (warmwater species) | " | No | - | Yes | 6 months |
| 163.72-2 | Acute toxicity to aquatic invertebrates | " | No | - | Yes | 6 months |

## PRODUCT-SPECIFIC DATA REQUIREMENTS FOR FORMULATED PRODUCTS

## Product Chemistry

Table 2

| Guideline Citation | Name of Test | Composition Characteristics | Does EPA Have Data To Satisfy This Requirement ? | Biblio-graphic Citation | Must Data Be Submitted Under FIFRA 3(c)(2)(B) ? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| 163.61-3 | Product identity and disclosure of ingredients | Any percentage active ingredient | No | - | Yes | 6 months |
| -4 | Description of manufacturing process | " | No | - | Yes | 24 months |
| -5 | Discussion on formation of unintentinal ingredients | " | No | - | Yes | 24 months |
| -6 | Declaration and cetification of ingredients limits | " | No | - | Yes | 6 (24mos.*) |
| -7 | Product analytical methods and data | " | No | - | Yes | 6 months |
| 163.61-8(1) | Color | " | No | - | Yes | 6 months |
| -8(2) | Odor | " | No | - | Yes | 6 months |
| -8(8) | Density or specific gravity | " | No | - | Yes | 6 months |
| -8(9) | Boiling point | " | No | - | Yes | 6 months |
| -8(10) | Vapor pressure | " | No | - | Yes | 6 months |
| -8(11) | pH (Manufacturing-use product and the technical) | " | No | - | Yes | 6 months |
| -8(12) | Storage stability | " | No | - | Yes | 6 months |
| -8(13) | Flammability | " | No | - | Yes | 6 months |
| -8(17) | Viscosity coefficient (Technical) | " | No | - | Yes | 6 months |
| -8(18) | Corrosion characteristics | " | No | - | Yes | 6 months |

* For impurities at 0.1% or less, information need not be submitted until 24 mos.

## PRODUCT-SPECIFIC DATA REQUIREMENTS FOR FORMULATED PRODUCTS

### Environmental Fate

Table 2 cont'd

| Guideline Citation | Name of Test | Composition Characteristics | Does EPA Have Data to Satisfy This Requirement ? | Bibliographic Citations | Must Data Be Submitted Under FIFRA 3(c)(2)(B)? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| 163.62-7 (c) | Hydrolysis | Any percentage active ingredient | No | - | Yes | 6 months |

PRODUCT - SPECIFIC DATA REQUIREMENTS FOR FORMULATED PRODUCTS

Toxicology

Table 2 cont'd

| Guideline Citation | Name of Test | Composition Characteristics | Does EPA Have Data to Satisfy This Requirement ? | Bibliographic Citations | Must Data Be Submitted Under FIFRA 3(c)(2)(B)? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| | | 1. All Ready-to-use | | | | |
| 163.81-1 | Acute Oral Toxicity | * | Yes | Warf 1976 MRID 00001101 | No | - |
| 163.71-2 | Acute Dermal Toxicity | * | Yes | Davidson 1960 MRID # 00001139 | No | - |
| 163.81-3 | Acute Inhalation Toxicity | * | Yes * | - | No | - |
| 163.81-4 | Primary Eye Irritation (Rabbit) | * | + Some (Incomplete) | Davidson 1960 MRID # 00001139<br>Warf 1976 MRID # 00001101 | Yes | 6 months |
| 163.81-5 | Primary Dermal Irritation (Rabbit) | * | + Some (Incomplete) | Davidson 1969 MRID # 00001139<br>Warf 1976 MRID #00001101 | Yes | 6 months |
| 163.81-6 | Dermal Sensitization (Guinea Pig) | * | + Some (Incomplete) | Ambrose 1959 MRID # 00001051 | Yes | 9 months |
| | | 2. All Pressurized Liquid | | | | |
| 163.81-1 | Acute Oral Toxicity | * | Yes | Warf 1975a MRID 00001085<br>Warf 1975b MRID 00001086<br>Howard 1971 00001080 | No | - |
| 163.81-2 | Acute Dermal Toxicity | * | Yes* | - | No | - |
| 163.81-3 | Acute Inhalation Toxicity | * | Yes | Warf 1975 MRID 00001086 | No | - |
| 163.81-4 | Primary Eye Irritation (Rabbit) | * | Some | Warf, 1975b MRID # 00001085<br>Durloo & Woodward 197b MRID 00001082 | Yes | 6 months |

* This information has been extrapolated from other tests, and is adequate without further testing.
+ See Chapter 5, Topical Discussions.

PRODUCT - SPECIFIC DATA REQUIREMENTS FOR FORMULATED PRODUCTS

Toxicology

Table 2 cont'd

| Guideline Citation | Name of Test | Composition Characteristics | Does EPA Have Data to Satisfy this Requirement | Bibliographic Citations | Must Data Be Submitted Under FIFRA 3(c)(2)(B)? | Time Allowed Before Submission |
|---|---|---|---|---|---|---|
| 163.81-5 | Primary Dermal Irritation (Rabbit) | Pressurized Liquid | Some | Johnson 1972 MRID # 00001873<br>Warf 1975a MRID # 00001805<br>Warf 1975b MRID # 00001806<br>Durloo & Woodland 9171b MRID # 00001801 | Yes | 6 months |
| 163.81-6 | Dermal Sensitization (Guinea Pig) | Pressurized Liquid | No | - | Yes | 9 months |
| | | 3. All Impregnated Materials | | | | |
| 163.81-1 | Acute Oral Toxicity | * | Yes * | - | No | - |
| 163.81-2 | Acute Dermal Toxicity | * | Yes * | - | No | - |
| 163.81-3 | Acute Inhalation Toxicity | * | Yes * | - | No | - |
| 163.81-4 | Primary Eye Irritation (Rabbit) | * | + Some (Incomplete) | - | Yes | 6 months |
| 163.81-5 | Primary Dermal Irritation (Rabbit) | * | No | - | Yes | 6 months |
| 163.81-6 | Dermal Sensitization (Guinea Pig) | * | No | - | Yes | 9 months |

* This information has been extrapolated from other tests, and is adequate without further testing.
+ See Chapter 5, Topical Discussions.

## PRODUCT-SPECIFIC DATA REQUIREMENTS FOR FORMULATED PRODUCTS

### Efficacy

Table 3

| Target Pest | Acceptable Use Sites (No Data Required) | Use Sites for which Data are Required | Must Data be Submitted to Support Duration Claims? |
|---|---|---|---|
| Biting Flies (black flies, sandflies and Ceratopogonidae); | Skin<br>Clothing<br>Tents and Bedrolls<br>Screens | Outdoor Mist | Yes |
| horseflies | None | Skin,Clothing, Tents and Bedrolls, Screens | Yes |
| Chiggers | Skin | *Clothing<br>*Tents and Bedrolls<br>Outdoor mist | Yes |
| Deerflies | Skin<br>Clothing<br>Tents and Bedrolls | Outdoor Mist | Yes |
| Fleas | Skin<br>Clothing<br>Tents and Bedrolls | Outdoor Mist | Yes |
| Leeches | Skin<br>Clothing<br>Tents and Bedrolls | Outdoor Mist | Yes |
| Mosquitoes | Skin<br>Clothing<br>Tents and Bedrolls<br>Screens | Outdoor Mist | Up to 2 hrs. may be claimed without data for acceptable sites. |
| Stable flies | Skin<br>Clothing<br>Tents and Bedrolls | Outdoor Mist | Up to 2 hrs. may be claimed without data for acceptable sites. |

## III. PRODUCT CHEMISTRY

### A. Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes, but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further, to assure that the composition of the product as marketed will not vary from the composition evalutated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, and the upper limits only for some unintentional ingredients. Subpart D (43 FR 29696, July 10, 1978) suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytic method.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., melting and boiling point data, ambient vapor pressure and solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g., flammability, corrosivity or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

### B. Disciplinary Review

#### 1. Chemistry Profile

Deet, (N,N-diethyl-m-toluamide), is an all-purpose individual insect repellent which contains a minimum of 95% of the meta isomer, the most effective form of diethyl toluamide, as a technical active ingredient.

Technical Deet is a nearly colorless liquid with a faint characteristic odor. It is relatively stable, highly hygroscopic and sensitive to light. Technical Deet is practically insoluble in water and glycerin but miscible with several organic solvents. It has a specific gravity of 0.990-1.000 at 25°C, a boiling point of 111°C at 1 mm Hg, and a vapor pressure of $1.67 \times 10^{-3}$ mm Hg at 25°C.

Technical Deet, as it is considered under this standard, is a "manufacturing-use product" which is intended for (re)formulation or repackaging for end use as a "formulated product." End use products are formulated as solutions, lotions, gels, aerosol sprays, sticks and impregnated towelettes. Although several multiple active ingredient products containing Deet are currently registered, this Registration Standard covers only those products which contain Deet as the single active ingredient. The amount of Deet in these products ranges from 11.27% - 100% of the product composition by weight.

## PRODUCT-SPECIFIC DATA REQUIREMENTS FOR FORMULATED PRODUCTS

### Efficacy

Table 3 Con't

| Target Pest | Acceptable Use Sites (No Data Required) | Use Sites for which Data are Required | Must Data be Submitted to Support Duration Claims? |
|---|---|---|---|
| Ticks | None | Skin<br>Clothing<br>Tents and Bedrolls<br>Outdoor Mist | Yes |

* Submit calculations which demonstrate that the product will deposit a minimum of 1 gm. AI/sq. ft., of treated material when used properly.

### 2. Generic Data Gaps

All of the generic data needed to evaluate the continued registerability of products to which this Standard applies are listed in Tables 1 and 2, Chapter 2.

### 3. Required Labeling

All technical and formulated Deet products must bear appropriate product chemistry labeling as specified in the Guidance Package which accompanies this Standard.

## C. Topical Discussions

In accordance with each of the topical discussions listed below, a detailed explanation of the minimum data that the Agency requires in order to adequately assess a pesticide's product chemistry can be found in the "Proposed Guidelines for Registering Pesticides" of July 10, 1978 (43 FR Part 163.61-2).

| Data Requirement | Guidelines Section |
|---|---|
| Technical Deet | |
| Chemical Identity | 163.61-3 |
| Manufacturing Process | 163.61-4 |
| Discussion of Formation of Pesticide Products | 163.61-5 |
| Percentages of Components in Unintentional Ingredients | 163.61-6 |
| Product Analytical Methods and Data | 163.61-7 |
| Physical/Chemical Properties- | |
| Color | 163.61-8(c)1 |
| Odor | 163.61-8(c)2 |
| Solubility (in quantitative terms) | 163.61-8(c)4 |
| Stability | 163.61-8(c)5 |
| Octanol/Water Partition Coefficient | 163.61-8(c)6 |
| Physical State | 163.61-8(c)7 |
| Specific Gravity | 163.61-8(c)8 |
| Boiling Point | 163.61-8(c)9 |
| Vapor Pressure | 163.61-8(c)10 |
| Viscosity | 163.61-8(c)17 |
| Corrosion Characteristics | 163.61-8(c)18 |
| pH Measurement | 163.61-8(c)11 |
| Storage stability | 163.61-8(c)12 |
| Flammability (flash point by closed cup method) | 163.61-8(c)13 |
| b. Formulated Deet | |
| Chemical Identity | 163.61-3 |
| Manufacturing Process | 163.61-4 |
| Discussion on Formation of Unintentional Ingredients | 163.61-5 |
| Percentages of Components in Pesticide Products | 163.61-6 |
| Product Analytical Methods and Data | 163.61-7 |
| Physical/Chemical Properties- | |
| Color | 163.61-8(c)1 |
| Odor | 163.61-8(c)2 |

| | |
|---|---|
| Physical State | 163.61-8(c)7 |
| Density or specific gravity | 163.61-8(c)8 |
| Boiling point | 163.61-8(c)9 |
| Vapor pressure | 163.61-8(c)10 |
| pH Measurement | 163.61-8(c)11 |
| Storage stability | 163.61-8(c)12 |
| Flammability (flashpoint, flame extension) | 163.61-8(c)13 |
| Viscosity | 163.61-8(c)17 |
| Corrosion characteristics | 163.61-8(c)18 |

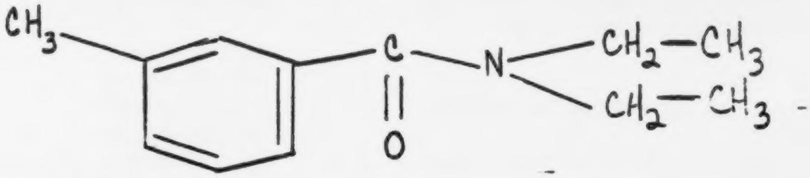
### a. Technical Deet

#### (1) Chemical Identity

"Deet" is the acceptable common name of the Entomological Society of America for N,N-diethyl-m-toluamide. The American National Standards Institute does not recognize Deet as the common name for N,N-diethyl-m-toluamide.

The name "Deet" will be routinely used in this Registration Standard in lieu of the more complex chemical name or of its trade names. Trade names for Deet include: Metadelphene$^{R}$ (Hercules, Inc.), OFF$^{R}$ (S.C. Johnson & Son,Inc.), and MGK Diethyltoluamide$^{R}$ (McLaughlin-Gormley-King Co.).

Deet is a diethyltoluamide consisting primarily of 95% of the meta isomer; it is an all-purpose individual insect repellent. Its molecular configuration is shown below:



#### (2) Manufacturing Process

In general, the open literature describes four methods of synthesizing N,N-diethyl-toluamides:

- acid-chloridizing m-toluic acid and then reacting with diethylamine in the presence of a catalyst in an organic solvent;
- reacting m-toluic acid and diethylamine with an appropriate catalyst in a continuous vapor-phase;
- reacting m-toluic acid and diethylamine in an anhydrous acetic acid medium; and
- reacting m-toluic acid with diethylamine in the presence of N-mono-ethyl-m-toluamide under pressure and raised temperature.

In addition, there are several other means of producing N,N-diethyl-m-toluamide in a laboratory; however, these procedures are not economical for continuous large scale industrial operation.

No data were submitted concerning the specific procedures, equipment and manufacturing conditions required for commercial production of the chemical.

### (3) Discussion on Formation of Unintentional Ingredients

The chemical reactions employed in the synthesis and purification of any active ingredient might cause potentially harmful impurities to be produced. The presence of manufacturing impurities is dependent upon the nature of the manufacturing process used.

Data considered as "Confidential Business Information" concerning the formation of each substance that might reasonably be identified as present in technical Deet were reported by McLaughlin, Gormley, King Company and Pfizer, Inc. The data fulfill requirements for these particular registrants. A data gap exists for other registrants.

### (4) Percentages of Components in Pesticide Products

Technical Deet contains a minimum of 95% of the active ingredient, N,N-diethyl-m-toluamide. Depending upon the manufacturing process used, up to about 5% of technical impurities (including moisture) can be expected.

### (5) Product Analytical Methods and Data

Although some of the manufacturing impurities of technical Deet have been identified by its manufacturers (McLaughlin, Gormley, King, Company, 1976, MRID # GS0002014); Pfizer Inc., 1976, 00001036), the methods that were used in the analyses were not described.

### (6) Physical/Chemical Properties

Color: Not darker than Hazen number 100 (Hercules Powder Co., 1957 MRID #00001025).

Odor: Nearly odorless, or has a characteristic faint odor depending on the purity of technical Deet and the kind of manufacturing process used (S.C. Johnson & Son, Inc., 1977 MRID # 00001100).

Solubility: The solubility of technical Deet was reported as follows (Cutter Laboratories, 1975 MRID#00001008):

practically insoluble in water
practically insoluble in glycerin
miscible with ethanol
miscible with ether
miscible with isopropanol
miscible with chloroform
miscible with carbon disulfide

The proposed guidelines state that solubility, preferably in g/100 ml of solvent at 20°C (68°F), or reported in other terms such as ppm (mg/kg) is required for the technical chemical.

Stability: Technical Deet is a relatively stable compound. It is highly hygroscopic and sensitive to light. When stored in a closed container protected from light it is regarded as being stable for at least one year (S.C. Johnson & Son, Inc., 1977 MRID #00001100).

Octanol/Water Partition Coefficient: No coefficient has been reported.

Physical State: Technical Deet is a liquid (Hercules, Inc., 19?? MRID #00001069).

Specific Gravity: The specific gravity of technical Deet ranges from 0.990 - 1.000 at $25^{\circ}$C (Hercules, Inc., 19?? MRID #0001068).

Boiling Point: At 1 mm Hg. the boiling point of technical Deet is $111^{\circ}$C (S.C. Johnson & Son, Inc. MRID #00001100; Blaine, R.L. *et al* ., 1974 MRID #05002553).

Vapor Pressure: $1.67 \times 10^{-3}$ mm Hg at $25^{\circ}$C (Blaine, R.L. *et al* ., 1974 MRID #05002553).

pH: none reported

Storage Stability: none reported

Flammability: The flashpoint (open cup) for technical Deet ranges from $150^{\circ}$C - $155^{\circ}$C (Hercules, Inc., 1972 MRID # 00001152; S.C. Johnson & Son, Inc., 1977 MRID# 00001100).

Viscosity: The viscosity for technical Deet was reported as 13.3 centipoises at $30^{\circ}$C (Hercules, Inc., 1972 MRID # 00001152; S.C. Johnson & Son, Inc., 1977 MRID# 00001100).

Corrosion Characteristics: Technical Deet has no corrosive action on most metals; however, metal containers may be corroded due to the presence of one or more of the other ingredients in the formulated product. To prevent the possibility of corrosion, a three-quarter or one-pound tin plate is recommended. Because excessive moisture can cause corrosion of pressurized containers, Deet is made available almost entirely free of water. As a hygroscopic agent, Deet should be protected from possible moisture pick-up in handling (Hercules Powder Co., 1957 MRID #00001025).

Submittal of Samples: Applicants for registration or reregistration will be notified at the time of application with regard to the submission of samples.

### b. Formulated Deet

#### (1) Chemical Identity

There are no data available on the chemical identity of Deet formulations. This constitutes a data gap.

### (2) Manufacturing Process

There are no data available on the manufacturing process of Deet formulations. This constitutes a data gap.

### (3) Discussion on Formulation of Unintentional Ingredients

No data have been submitted. This constitutes a data gap.

### (4) Percentages of Components in Pesticides Products

Data on currently registered formulated Deet products are listed below.

| Type of Formulation | % Active Ingredient |
|---|---|
| Solution, Ready-to-Use | 15.0 - 99.9% |
| Pressurized Liquid | 12.5 - 75.0% |
| Impregnated Material | 11.7 - 38.8 % |

The compositional data as to inert ingredients will not be discussed because of the extensive number of Deet products. The data were given full consideration by the Agency in developing this Registration Standard.

### (5) Product Analytical Methods and Data

No method has been submitted for determining or measuring any of the impurities in Deet products; however, the literature indicated the identification and measurement of these impurities by thin layer and gas chromatography (Voronkina, T.M., et al., 1971, 05000597).

Methods for detecting and measuring the active ingredient Deet in registered products have been submitted (Sarmienta and Beroza, 1975, 05000048; Cutter Laboratories, 1975, 00001008; Pfizer, Inc, 1976, 00001036).

### (6) Physical/Chemical Properties

No data pertaining to the physical/chemical properties of Deet products were submitted. Accordingly, none of the minimum data requirements listed at the beginning of the Topical Discussions are satisfied and this constitutes a data gap.

# IV. ENVIRONMENTAL FATE

## A. Disciplinary Review

### 1. Use Profile

The major use site for Deet is human skin. Formulations registered for such use are labeled to warn against contact with eyes or lips; pressurized liquids are not to be sprayed directly into the face.

Deet is also registered for application to household pets. Labels advise against contact with eyes, lips and open wounds.

Clothing, tents and bedrolls may be treated with Deet formulations registered for these uses. Labels advise against application to rayon, spandex, dynel and verel fabrics.

Other registered uses for Deet are application to screens and screen doors. Labels on formulations intended for these uses caution against application to plastics, painted surfaces and other finishes.

Although all of the above uses can occur outdoors, residues occurring in the environment after application will be considered insignificant for purposes of this Standard. Likewise, while Deet can be applied around food in picnic and camping areas, residues on food items are considered insignificant for purposes of this Standard.

### 2. Environmental Fate Profile

Registered outdoor uses of Deet are not expected to result in the introduction of significant amounts of this pesticide into the environment. However, technical Deet can potentially enter the aquatic environment through indirect or accidental discharge into lakes, streams or wastewater treatment systems. The data necessary, but currently not available, for an evaluation of technical Deet's effect on the aquatic environment are hydrolysis and activated sludge metabolism studies; formulated Deet can also potentially enter wastewater treatment systems and for this reason hydrolysis studies are necessary. The only portion of an environmental fate profile necessary to this Standard is an evaluation of these effects.

### 3. Exposure Profile

#### a. Technical Deet

For persons involved in the manufacture, handling, storage or shipment of technical Deet, this Standard will not include an assessment of hazard because the responsibility of establishing standards for such exposure falls within the jurisdiction of the Occupational Safety and Health Administration.

#### b. Formulated Deet

Ready-to-use solutions, pressurized liquids and impregnated materials containing Deet are registered for use on all exposed human skin areas. It is estimated that this use accounts for 99% of the single active ingredient Deet produced (Hales, Y. and Radtke, 1980 MRID #GS0002001).

In 1978, an estimated 38% of the total U S population used an insect repellent, although not all of these products contained Deet (S.C. Johnson and Co. 1979 MRID #GS0002002). Highest use of insect repellent was reported in the Southwest (49%) and lowest on the Pacific Coast (27%). Of the various products used (Deet containing and otherwise), 73% were pressurized liquids, 19% were ready-to-use solutions, and 8% were impregnated materials. Deet concentrations in the pressurized liquid products (the most widely used) ranged from 15 to 20%. Based on these data, it is estimated that 22% of the general population is exposed to pressurized liquid products that contain 15 to 20% Deet as an active ingredient. Remaining usage is divided among other types of products and pressurized formulations.

An Insecticide User Profile prepared by S.C. Johnson Co, Inc. in 1975 provided most of the available data on exposure of the general population to Deet (MRID #GS0002003). The study is not considered to be fully representative of the U.S. population because respondents were all S.C. Johnson employees. Nevertheless, these data are useful in the absence of other information about the extent of use of Deet by the general population.

Based on the S.C. Johnson Co. data, average usage of Deet products by the general population will result in an average daily exposure to active ingredient ranging from 0.944 g (for a 20% a.i. product) to 3.5 g (for a 75% product). This is equivalent to 13.5 - 50.6 mg/kg/day for a 70 kg man and 15.7-59 mg/kg/day for a 60 kg woman. The Johnson data also estimated usage by 90% or less of the general population to be 1.06g and 3.98g per day for 20% and 75% products, respectively. This is equivalent to 15.0 - 56.8 mg/kg/day for a 70 kg man and 17.7-66.3 mg/kg/day for a 60 kg woman.

Additional data provided by S.C. Johnson for a 15% pressurized liquid formulation related grams of product applied on the users forearms to the number of users applying a specific amount of the product. These data, based on a survey of 71 people, indicate that 90% of those interviewed used 1.4 grams of product or less per forearm and 99% used 2.9 grams or less per forearm. From these data the Agency calculated, through extrapolation, that 99% of users are exposed to 11.0 g/day or less of formulation applied to all exposed skin. This is equivalent to a daily exposure of 1.65 grams of Deet or 23.5 mg/kg/day for a 70 kg man using a 15% formulation. If a 75% Deet product were used at the 11.0 g/day rate assumed above, the exposure would 8.23 g/day of active ingredient or 117.6 mg/kg/day for a 70 kg man.

Thus, based on the S.C. Johnson survey, 1% of users may be exposed to greater than 1.65 g/day assuming use of a 15% product. In the case of a 75% product used at the rate of 11 g/day, exposure would be 5 times that of the 15% product, or 8.25 g/day/ of active ingredient.

The Agency recognizes that Deet products composed solely of technical Deet are also available for use by the general population. Although no data are available on use rates of these products, the Agency concludes that exposures will be proportionately higher than those presented above if the products are applied with the same frequency.

It must be noted that all of the above calculations reflect Deet exposure at the surface of the skin only. Data reveiwed by Agency toxicologists, and explained in detail in Chapter V, show that 10% of Deet applied directly to the body is absorbed through the skin. All of the available exposure data on the general population and the Agency's estimates based on these data are summarized in Table 4.

Table 4

Estimated Exposure to Deet

| Formulation (% Deet) | Average Daily Exposure 1/ | | Maximum use by 90% of Subjects 2/ | | Maximum use by 99% of Subject (Based on 11.0 gr product/day) | |
|---|---|---|---|---|---|---|
| | gram/day | mg/kg/day | gram/day | mg/kg/day | grams/day | mg/kg/day |
| 15% | ND | ND | ND | ND | 1.65 | 23.40 |
| 20% | 0.944 | 13.50<br>* 15.70 | 1.06 | 15.00<br>* 17.70 | ND | ND |
| 30% | 1.42 | 20.23 | 1.59 | 22.70 | ND | ND |
| 50% | 2.36 | 33.70 | 2.65 | 37.80 | ND | ND |
| 75% | 3.54 | 50.60<br>* 59.00 | 3.98 | 56.8<br>* 66.3 | +8.23 | +117.6 |

1/ Based on use of 16-20 g. of formulation per 4-week period (S.C. Johnson & Son, Inc. 1979 MRID # GS0002002).

2/ Based on use of 48 g. of formulation per 4-week period (S.C. Johnson & Son, Inc. 1979 MRID #GS0002002).

* Figures assume a 60 Kg woman. All other figures assume a 70 Kg man.

Figures assume a 60 Kg woman. All other figures assume a 70 Kg man.

+ Based on extrapolation from data on application to forearm only.
ND = No data available

Several occupational groups are expected to experience exposures higher than those of the general population. Military personnel have been identified as a high-exposure group based on an estimated usage of 1 ml of a 75% formulation approximately 60 times per year. This is equivalent to a total annual exposure of 43 grams of active ingredient to each of approximately 628,000 exposed individuals, or 10.7 mg/kg/day ( Hales, Y and H.E. Radtke 1980, MRID #GS0002001).

Other high exposure groups include persons engaged in such outdoor occupations such as forestry, research, fishing, lumbering, park and refuge maintenance, outdoor sports and gardening. The only quantitative exposure data submitted relate to a research biologist in the Florida Everglades, who reported using 2 one-ounce bottles of 28.74% Deet per week on the skin, and 2 two-ounce cans of 71.25% Deet per week on clothing (Mazzotti, F. 1980 MRID #GS0002004). Applications were made 4 days per week from May to October. Based on these data, the Agency estimates that exposure is 4.25 g/day or 60.7 mg/kg/day, assuming a body weight of 70 Kg. Application to clothing, also based on a 4-day week, would be 20.2 g/day; an undetermined amount of the Deet applied to clothing would to be transferred to the skin. These exposure estimates are almost three times as great as the maximum daily exposure to 90% of the general population reported by S.C. Johnson Co. for a 30% active ingredient product (63.4 mg/kg/day vs. 22.7 mg/kg/day).

In conclusion, an average exposure to Deet active ingredient is probably in the range of 10-20 mg/kg/day, with 90% of the population exposed to less than about 35 mg/kg/day. It has been estimated that about 1% of users apply 11.0 gm or more per day to exposed skin areas. Thus, use of a 20% formulation would result in an exposure of 31 mg/kg/day; for a 75% formulation, 117.6 mg/kg/day; and for a 100% active product, 157 mg/kg/day, The above figures for exposure are only estimates based on limited data for the numbers of grams of products applied by users. Few data were available on the actual formulations used, although pressurized liquid products containing 15-20% active ingredient are claimed to be the most popular. The Agency acknowledges that the above estimates are based on limited data taken from a small sample group; however, they represent all the data currently available.

Occupational exposures could not be fully evaluated, although available data indicate that military personnel may experience an annual exposure of up to 10.7 mg/kg/day and a research biologist in the Florida Everglades is exposed to 63.4 mg/kg/day. Although these exposure levels to military personnel appear to be about the same as those of the general population, they occur with greater frequency throughout the year; thus, the total annual exposures are likely to be much greater.

Before a complete exposure profile is prepared, additional human exposure data will be required, under Data Gaps below.

### 4. Data Gaps

To support the registration of Deet products, it is necessary to submit the following data, which are explained in detail in the "Proposed Guidelines for Registering Pesticides in the United States" (43 FR 29696, July 10, 1978).

| | Guidelines Section |
|---|---|
| a. Technical Deet | |
| Hydrolysis | 163.62-7 (a) |
| Activated Sludge | 163.62-8 (g) |
| b. Formulated Deet | |
| Hydrolysis | 163.62.7 (g) |
| Human Exposure Data | Special Requirements<br>(FIFRA Sec 3(c)(2)(B)) |

1. Statistical data giving the percentage of total U.S. population exposed to Deet products, broken down by sex, age group (adults, teenagers, children, and pregnant women). Data on pregnant women are requested as a result of questions of possible embryotoxicity (See Chapter V);

2. Statistical data giving the geographical breakdown of the use frequency and amounts of Deet products (i.e., the Southeast, Gulf States and Pacific Northwest);

3. Data estimating the expected "average" or "normal" maximum exposure per day to an individual using Deet products. The data must encompass 90 to 99% of the total population exposed to such products. In addition, worst case and occupational exposure situations must be identified, including situations that could be reasonably expected to occur, such as application to large areas of the skin, frequent applications per day, etc. These estimates should be given for each of the population groups specified above;

4. Identification of the types of Deet products most commonly used and the percent active ingredient contained in each product.

5. Required Labeling

There are no environmental fate labeling requirements for technical or formulated Deet.

B. Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section in the "Proposed Guidelines for Registering Pesticides in the United States" (43 FR 29696, July 10, 1978) which explains the minimum data that the Agency requires to adequately assess the environmental fate of Deet. Special data requirements are also specified.

1. Technical Deet

| Data Requirement | Guidelines Section |
|---|---|
| Physico-Chemical Transformation (Hydrolysis) | 163.62-7 (a) |
| Metabolism (Activated Sludge) | 163.62-8 (g) |

a. Hydrolysis

Technical Deet could potentially enter natural water via industrial discharge, and as a result of disposal and cleanup of containers and equipment. Hydrolysis data are therefore required on technical Deet to support the registration of technical Deet. No data on the hydrolysis of Deet are available; this constitutes a data gap.

### b. Activated Sludge Metabolism

For the assessment of Deet's potential effect on the wastewater treatment process through indirect discharge into treatment systems, an activated sludge metabolism study is required. No data on activated sludge metabolism of technical Deet are available; this constitutes a data gap.

## 2. Formulated Deet

| Data Requirement | Guidelines Section |
|---|---|
| Physico-Chemical Transformation (Hydrolysis) | 163.62-7 (a) |
| Human Exposure | Special requirement<br>FIFRA Sec. 3(c)(2)(B) |

### Hydrolysis

Data are required for the same reasons as those listed under part (a) of this section. A data gap exists for formulated Deet.

# V. TOXICOLOGY

## A. Disciplinary Review

### 1. Toxicology Profile

### a. Technical Deet

Sufficient data were available to assess the acute toxicity of technical Deet. The oral $LD_{50}$ in rats (male rats = 2.43 ml/kg; female rats = 1.78 ml/kg) indicates a potentially low acute oral toxicity in humans. The dermal $LD_{50}$ in rabbits (3.18 ml/kg or greater) indicates a potentially low dermal toxicity in humans. Likewise, the inhalation $LC_{50}$ in rats (5.95 mg/l) indicates a low acute inhalation toxicity in humans.

Some information was provided on the irritation and sensitization potential of technical Deet. In an eye irritation study conducted on rabbits, 0.1 ml of technical Deet induced marked transitory irritation and opacity. This study strongly suggests that technical Deet is potentially a severe eye irritant. Dermal irritation and sensitization studies conducted on rabbits and guinea pigs, respectively, demonstrated that technical Deet is not a potential skin irritant on sensitizer. No adequate subchronic toxicity data were available. In several inadequate subchronic (90-day) dermal studies, technical Deet was administered to rabbits. Conflicting results and inappropriate reporting preclude the use of these studies to assess the subchronic dermal toxicity potential; additional testing is required. However, an adequate subchronic inhalation study conducted on rats showed no abnormal behavioral signs or pathology at 7.5 mg/l; the lowest effect level was 15.0 mg/l, the effect being abnormal sperm morphology. Additional special testing was conducted on sperm count, spermhead, morphology and sperm viability in rats dermally administered doses of 0, 100, 300, or 1000 mg/kg/day of Deet 5 days each week for 9 weeks. There were no compound-related effects at any dose.

Inadequate chronic toxicity data were available to assess long-term effects of technical Deet. Supplementary studies [1] conducted on mice and rabbits demonstrated no oncogenic potential; however, inappropriate testing protocol precludes the use of these studies and additional data are required. In addition, conflicting teratogenicity studies were performed. An adequate dermal teratology test conducted using rabbits showed no effect at the highest dose of 5000 mg/kg/day. However, an oral teratology test conducted on rats resulted in a possible embryotoxic effect at 80 mg/kg/day; this test is not adequate to satisfy the data requirement due to inappropriate testing protocols and is therefore considered supplementary. An additional dermal teratology test is required in the same species to clarify questions raised by the first study. No adequate data were available to assess the reproduction toxicity potential of technical Deet. Mutagenicity testing is incomplete. The available mutagenicity data demonstrate that technical Deet does not induce reverse mutations in S. typhimurium. No dominant lethal effects at the dose tested (600 mg/kg in male mice) were indicated in a supplementary study (deemed supplementary because the maximum tolerated dose was not used). However, the

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1 / For the purposes of this Standard, a supplementary study is one that does not meet required testing standards but does provide some relevant information.

dominant lethal study showed a reduction of implants in pregnant females, suggesting that further reproduction testing is necessary. In addition, further mutagenicity testing is required to satisfy data requirements.

The available metabolism data were incomplete, but animal data suggest that Deet is absorbed (rabbit is 36%; male rat is 43%; female rat is 32%; humans is 8-10%), rapidly excreted (rats = 68% in 24 hrs) and not bioaccumulated. However, no metabolite identification data are available and additional metabolism testing is required.

### b. Formulated Deet

#### (1)Ready-To-Use (RTU)

Based on available data (see Topical Discussions for details), statements of formula and the intended pattern of use for Deet, the acute toxicity (oral, dermal, inhalation), irritation (eye and dermal) and dermal sensitization potentials are as indicated in Table 5.

Table 5

Summary of Acute Toxicity Data on Ready-To-Use Formulations

| Toxicity Testing | Existing RTU Products | | | |
|---|---|---|---|---|
| | 15-25% | 40-55% | 75% | 100% |
| Acute Oral | Low | Low 1/ | Low 1/ | Low |
| Acute Dermal | Low 1/ | Low 1/ | Low 1/ | Low |
| Acute Inhalation | Very low 1/ | Very Low 1/ | Very Low 1/ | Very Low |
| Primary Eye | Low | Data Gap 2/ | Data Gap 2/ | Severe eye irritation |
| Primary Dermal | Very Low | Data Gap 2/ | Data Gap 2/ | Very low |
| Primary Sensitization | Data gap 2/ | Data Gap 2/ | Data Gap 2/ | No Sensitization |

1/ Based on data extrapolation
2/ Testing is required

#### (2)Pressurized Liquid (PrL)

Based on the available data (See Topical Discussions for details), statements of formula, and the intended pattern of Use for Deet, the acute toxicity (oral, dermal, inhalation), irritation (eye and dermal) and dermal sensitization potentials are indicated in the Table 6.

Table 6

Summary of Acute Toxicity Data on Pressurized Liquid Formulations

| Toxicity Testing | Existing PrL Products 1/<br>12-30% | <br>75% |
|---|---|---|
| Acute Oral | Low | Low 2/ |
| Acute Dermal | Low | Low 2/ |
| Acute Inhalation | Very Low 2/ | Very Low 2/ |
| Primary Eye | Low | Data Gap 3/ |
| Primary Skin | Very Low | Data Gap 3/ |
| Primary Sensitization | Data Gap 2/ | Data Gap 3/ |

1/ Those existing PrL products which do not contain freon propellants
2/ Based on data extrapolation
3/ Testing is required

(3) Impregnated Material (ImM)

Based on available data (see Topical Discussions for details), statements of formula, and the intended pattern of use for Deet, the acute toxicity (oral, dermal, inhalation), irritation (eye and dermal) and dermal sensitization potentials are as indicated in Table 7.

Table 7

Summary of Acute Toxicity Data on Impregnated Material Formulations

| Toxicity Testing | Registered ImM<br>11-27% | Products<br>33% |
|---|---|---|
| Acute Oral ($LD_{50}$) | Low 1/ | Low 1/ |
| Acute Dermal ($LD_{50}$) | Low 1/ | Low 1/ |
| Acute Inhalation ($LC_{50}$) | Very Low 1/ | Very Low 1/ |
| Primary Eye | Data Gap 2/ | Data Gap 2/ |
| Primary Dermal | Data Gap 2/ | Data Gap 2/ |
| Primary Dermal Sensitization | Data Gap 2/ | Data Gap 2/ |

1/ Based on data extrapolation
2/ Testing is required

## 2. Toxicology Hazard Assessment

### a. Technical Deet

The information available to assess potential hazard as a result of chronic exposure is incomplete and inconclusive (see Topical Discussions and the Toxicology Profile for details). Therefore, the oncogenic, teratologic, mutagenic and reproduction effects resulting from chronic exposure to formulated Deet, based on testing of technical Deet, cannot be adequately evaluated. Several supplemental studies (dominant lethal mutagenicity, teratology, and subchronic inhalation toxicity) indicate possible reproductive toxicity. Although the data are only suggestive, it is imperative to conduct the necessary studies to resolve the questions of adverse effects.

### b. Formulated Deet

#### (1) Ready-To-Use

Because of the intended pattern of use for RTU Deet products, the likely routes of exposure are dermal and occasional accidental oral, eye, and inhalation. The existing RTU products have a low acute oral and inhalation toxicity potential; therefore, single accidental exposures are not expected to pose a hazard. Accidental eye exposure is potentially serious because corneal opacity has been noted in a technical product; therefore, extreme caution should be used when applying RTU products which contain more than 30% Deet. The information currently available to assess the primary dermal toxicity and dermal sensitization of RTU formulations is incomplete. Likewise, the data for chronic exposure is incomplete and therefore a chronic toxicity risk cannot be determined at this time.

#### (2) Pressurized Liquid (PrL)

Due to the intended pattern of use for PrL Deet products, dermal, and occasional accidental oral, eye, and inhalation exposure are the likely routes of exposure. However, the existing products have a low acute oral and inhalation toxicity potential; therefore, accidental exposures are not expected to pose a hazard. Accidental eye exposure is potentially serious as corneal opacity has been noted in a technical Deet product; therefore, extreme caution should be used when applying RTU products. The information currently available to assess the primary dermal toxicity and dermal sensitization is incomplete. Likewise, the data for chronic exposure to technical Deet is incomplete and therefore a chronic toxicity risk cannot be determined at this time.

#### (3) Impregnated Material (ImM)

Due to the intended pattern of use for ImM Deet products, dermal and occasional accidental oral, eye, and inhalation are the likely exposure routes.However, the existing products have a low acute oral and inhalation toxicity potential; therefore, these single accidental exposures are not expected to pose a hazard. Accidental eye exposure is potentially serious because corneal opacity has been noted in a technical Deet product. The information currently available to assess the primary dermal toxicity and dermal sensitization is incomplete. Likewise, the data for chronic exposure is incomplete; therefore, a chronic toxicity risk cannot be determined at this time.

### 3. Generic Toxicology Data Gaps

| Technical Deet | Guidelines Section: |
|---|---|
| Subchronic 90-day dermal (rabbits) | 163.82-3 |
| 2-yr Dermal exposure combined with oncogenicity (rat) | 163.83-2 |
| Dermal Oncogenicity (mouse) | 163.83-2 |
| Dermal Teratogenicity (rat) | 163.83-3 |
| Dermal Reproduction (rat) | 163.83-4 |
| Mutagenicity | 163.84-2<br>163.84-3<br>163.84-4 |
| Metabolism (identification of metabolites) | 163.85-1 |

**Formulated Deet**

| Ready-To-Use (RTU) | |
|---|---|
| Primary Eye Irritation (40-55% and 75%) (rabbit) | 163.81-4 |
| Primary Dermal Irritation (40-55% and 75%) (rabbits) | 163.81-5 |
| Dermal Sensitization (15-25%; 40-55%; 75%) (Guinea Pig) | 163.81-6 |

| Pressurized Liquid (PrL) | |
|---|---|
| Primary Eye Irritation (75%) (rabbit) | 163.81.4 |
| Primary Dermal Irritation (75%) (rabbit) | 163.81-5 |
| Dermal Sensitization (12-30%; 75%) (Guinea Pig) | 163.81-6 |

| Impregnated Material (ImM) | |
|---|---|
| Primary Eye Irritation (11.27% and 33%) (rabbit) | 163.81.4 |
| Primary Dermal Irritation (11.27% and 33%) (rabbit) | 163.81-5 |
| Dermal Sensitization (11.27% and 33%) (Guinea Pig) | 163.81-6 |

### 4. Required Labeling

All technical and formulated Deet products must bear appropriate acute toxicity labeling and statements of practical treatment as specified in the Gudiance Package which accompanies this Standard.

## B. Topical Discussions

### 1. Acute Oral Toxicity (163.81-1)

The minimum data requirement for testing acute oral toxicity ($LD_{50}$) is one test for the technical formulation and one test for each registered product, preferably using the laboratory rat.

#### a. Technical

Adequate acute oral toxicity studies were conducted as indicated in Tables 8 and 9.

Table 8

Acute Oral Toxicity of Technical Deet

| Animal | %m-DEET | $LD_{50}$ | Toxicity Category | Reference |
|---|---|---|---|---|
| Rat (M) | 90-100% | 2.43 ml/kg | III | Ambrose, 1959 MRID #00001051 |
| Rat (F) | 90-100% | 1.78 ml/kg | III | Ambrose, 1959 MRID #00001051 |
| Rat (M) | Unspecified | 2.68 ml/kg | III | Carpenter, et al., 1974 MRID #05000243 |
| Rat (M) | 95% | 3.29G/kg | III | U.S. Army, 1979 MRID #GS0002030 |
| Rat (F) | 95% | 2.42G/kg | III | U.S. Army, 1979 MRID #GS0002030 |
| Rat (M) | 95% (in corn oil) | 3.16G/kg | III | U.S. Army, 1979 MRID #GS0002030 |
| Rat (F) | 95% (in corn oil) | 2.17G/kg | III | U.S. Army, 1979 MRID #GS0002030 |

The above information is sufficient to satisfy the data requirement for acute oral toxicity for technical DEET. The data indicate that technical Deet should be assigned to Toxicity Category III for acute oral toxicity, which corresponds to a low potential acute oral hazard.

In additional testing using the ortho(o)-isomer and the para(p)-isomer, which occur as impurities in Deet, the acute oral toxicity in rats was as follows:

Table 9

Acute Oral Toxicity of o- and p- Isomers of Deet

| Animal | %-Deet | $LD_{50}$ | Toxicity Category | Reference |
|---|---|---|---|---|
| Rat (M/F) | 95% o-Deet | 1.21 g/kg | III | Ambrose & Yost, 1965 MRID #00001102 |
| Rat (M/F) | 95% p-Deet | 2.3 g/kg | III | Ambrose & Yost, 1965 MRID #00001102 |

The data indicate that o-Deet and p-Deet should be assigned to Toxicity Category III for acute oral toxicity, which corresponds to a potentially low acute oral hazard.

### b. Formulated Deet

#### (1) Ready-To-Use (RTU)

The acute oral $LD_{50}$ in the rat is 2.10 m/kg (Warf, 1976 MRID #00001101) for an 18% RTU product. The data indicate that the 18% RTU product should be assigned to Toxicity Category III for acute oral Toxicity.

Because oral toxicity studies place both technical deet and the 18% RTU product in Toxicity Category III, and because the inert ingredients in RTU Deet formulations are not expected to increase the acute oral toxicity potential, all existing RTU concentrations are placed in Toxicity Category III. Toxicity Category III corresponds to a low acute oral toxicity potential.

#### (2) Pressurized Liquid (PrL)

Adequate acute oral toxicity studies were conducted as reported Table 10.

Table 10
Acute Oral Toxicity of PrL Deet

| Animal | %m-DEET | $LD_{50}$ | Toxicity Category | Reference |
|---|---|---|---|---|
| Rat (M) | 15% | 5-10 ml/kg | III | Warf, 1975a, 1975b |
| Rat (F) | 15% | 2-10 ml/kg | III | Warf, 1975a, 1975b<br>MRID #00001085, #00001086 |
| Rat (M) | 30% | 2.61 ml/kg | III | Howard, 1971 |
| Rat (F) | 30% | 2.3 g/kg | III | Howard, 1971<br>MRID #00001080 |

The table shows that PrL products at 15% and 30% concentrations are in Toxicity Category III. Because technical Deet and the 15% and 30% PrL formulations are in Toxicity Category III, and because the inert ingredients in the PrL formulations are not expected to increase the acute oral toxicity potential, existing PrL products between 12% and 75% concentrations, except those that contain freon propellants, are classified in Toxicity Category III. Toxicity Category III corresponds to a low acute oral toxicity potential.

NOTE: Freon is regarded as a major hazard to the environment and its use in consumer products has been prohibited by the Agency. For all existing products which contain freon propellants the registrant must submit formulation statements with replacement propellants. The Agency will evaluate the new submissions on a case by case basis.

#### (3) Impregnated Materials (ImM)

No data were available for the assessment of the acute oral toxicity of ImM products. Because technical Deet is placed in Toxicity Category III) and because the inert ingredients in ImM products are not expected to increase the acute oral toxicity potential, all existing ImM products between 11% and 33% concentrations are placed in Toxicity Category III. Toxicity Category III corresponds to a low acute oral toxicity potential.

### 2. Acute Dermal Toxicity (163.81-2)

The minimum data requirement for testing acute dermal toxicity ($LD_{50}$) is one test for the technical product and one test for each registered formulation, preferably using the albino rabbit.

#### a. Technical

Adequate acute dermal toxicity studies were conducted as indicated in Table 11.

Table 11

| Animal | %m-DEET | $LD_{50}$ | Toxicity Category | Reference |
|---|---|---|---|---|
| Rabbit | 90-100% | greater than 4 ml/kg | III | Ambrose, 1959<br>MRID #00001051 |
| Rabbit | unspecified | 3.18 ml/kg | III | Carpenter, 1974<br>MRID #05000243 |
| Rabbit | 95% | 4.28 g/kg | III | U.S. Army, 1979<br>MRID #GS0002026 |

The data indicate that technical Deet should be assigned to Toxicity Category III for acute toxicity, which indicates a low potential acute dermal hazard.

The above data are sufficient to satisfy the data requirement for acute dermal toxicity for technical Deet.

#### b. Formulated Deet

##### (1) Ready-To-Use (RTU)

The acute dermal $LD_{50}$ in the rabbit (abraded and unabraded skin) is greater than 4 g/kg for a 15% RTU product (Davidow, 1960 MRID #00001139). The data indicate that the 15% product should be assigned Toxicity Category III for acute dermal toxicity.

Because acute dermal toxicity studies place both technical deet and the 15% RTU product in Toxicity Category III, and because the inert ingredients in RTU Deet formulations are not expected to increase the acute dermal toxicity potential, all existing RTU products between 15% and 75% concentrations are placed in Toxicity Category III. Toxicity Category III corresponds to a low acute dermal toxicity potential.

##### (2) Pressurized Liquid (PrL)

No data were available to assess the acute dermal toxicity of the existing PrL product. Because technical Deet is placed in Toxicity Category III, and because the inert ingredients in PrL products are not expected to increase the acute dermal toxicity potential, all existing PrL products between 12% and 75%

concentrations, except those that incorporate from propellants, are classified in Toxicity Category III. Toxicity Category III corresponds to a low acute dermal toxicity potential.

#### (3) Impregnated Materials (ImM)

No data were available to the assess the acute dermal toxicity of the existing ImM products. Because technical Deet is placed in Toxicity Category III, and because the inert ingredients in ImM products are not expected to incease the acute dermal toxicity potential, all existing ImM products between 11% and 33% are classified in Toxicity Category III. Toxicity Category III corresponds to a low acute dermal toxicity potential.

### 3. Acute Inhalation Toxicity (163.81-3)

The minimum data requirement for testing acute inhalation toxicity ($LC_{50}$) is one test on the technical chemical and on each manufacturing use and formulated product, preferably using the laboratory rat.

An acute inhalation toxicity ($LC_{50}$) test is required for each formulation that causes a respirable vapor, or for which 20% or more of the aerodynamic equivalent is composed of particles not larger than 10 microns.

#### a. Technical

A supplemental acute inhalation study was conducted on rats (Ambrose, 1959 MRID #0000105). The animals were exposed to an unspecified amount of technical Deet (85% A.I.) aerosol for 6 hours. Toxic signs observed were slight bloody discharge around the eyes and nose immediately after exposure; all rats appeared normal at 24 hours. All rats survived the exposure; histopathologic examination was negative. This study does not meet the data requirement for acute inhalation because the dose was not reported and therefore is considered supplementary.

An adequate acute inhalation study was conducted on male and female rats (U.S. Army, 1979 MRID #GS0002034). The animals were exposed to 0, 3.70, 4.26, 5.19, 5.48 or 5.95 mg/l of technical Deet for 4 hours. The $LC_{50}$ was calculated to be 5.95 mg/l which corresponds to Toxicity Category IV, indicating a very low acute inhalation toxicity potential.

The above data are sufficient to satisfy the acute inhalation toxicity data requirement for technical DEET.

#### b. Formulated

#### (1) Ready-To-Use (RTU)

No data were available to assess the acute inhalation toxicity of registered RTU products. Because technical Deet is placed in Toxicity Category IV, and because the inert ingredients in RTU products are not expected to increase the acute inhalation toxicity potential, all existing RTU products between 15% and 75% concentrations are placed in Toxicity Category IV. Toxicity Category IV corresonds to a very low acute inhalation toxicity potential.

### (2) Pressurized Liquids (PrL)

The available data were invalid to assess the acute inhalation toxicity of the 15% PrL product. Because technical Deet is placed in Toxicity Category IV, and because the inert ingredients in PrL products are not expected to increase the acute inhalation toxicity potential, all existing PrL products between 12% and 75% concentrations, except those that incorporate freon propellants, are placed in Toxicity Category IV. Toxicity Category IV, corresponding to a very low acute inhalation Toxicity potential.

### (3) Impregnated Material (ImM)

No data were available to assess the acute inhalation potential of existing ImM products. Because technical Deet is placed in Toxicity Category IV, and because the inert ingredients in ImM products are not expected to increase the acute inhalation toxicity potential, all existing ImM products between 11% and 33% concentrations are placed in Toxicity Category IV. Toxicity Category IV corresponds to a very low acute inhalation toxicity potential.

## 4. Primary Eye Irritation (163.81-4)

The minimum data requirement for primary eye irritation is one test for the manufacturing-use product and one test for each registered product, preferably using the albino rabbit.

### a. Technical/Manufacturing-Use Product

A primary eye irritation study was conducted on rabbits (Ambrose, 1959 MRID #00001051) using one drop (0.04 mg) of Deet. The Deet produced moderate edema and erythema and some "cloudiness" in 3 rabbits for 72 hours; after 5 days all eyes were normal. This study is not sufficient to meet data requirements for eye irritation because the scoring system used was not identified and the individual scores were not reported. It is therefore considered supplementary. However, this study does suggest that technical Deet is a potentially severe eye irritant in rabbits.

An adequate eye irritation study was conducted on rabbits (U.S. Army, 1979 MRID # GS0002025). A dose of 0.1 ml of technical Deet was instilled into the lower conjunction of the rabbit eye and evaluated by the method of Draize (1959). The following results were reported:

Table 12

Results of U.S. Army (1979) Eye Irritation Study

| Structure | Mean Draize Score | | | |
|---|---|---|---|---|
| | 24 hrs. | 48 hrs. | 72 hrs. | 7 days |
| Cornea | 0.5 | 0.2 | 0.0 | 0.0 |
| Iris | 0.2 | 0.0 | 0.0 | 0.0 |
| Conjunctivae | 2.7 | 1.0 | 0.4 | 0.0 |

This study indicates that technical Deet induced marked transitory eye irritation and transitory corneal opacification. This information indicates that technical Deet is irritating to the rabbit eye due to the transitory corneal opacity noted. This information is sufficient to satisfy the data requirement for primary eye irritation for technical Deet.

### b. Formulated Deet

#### (1) Ready-To-Use (RTU)

Two adequate primary eye irritation studies were conducted on existing RTU products as shown in Table 13.

Table 13

Primary Eye Irritation of RTU Deet

| Animal | %m-DEET | Dose | Results | Reference |
|---|---|---|---|---|
| Rabbit 1/ | 15% | 100 mg | Mild irritation at 48 hrs but absent at 72 hrs; no corneal opacity. | Davidow 1960, MRID #00001139 |
| Rabbit 1/ | 15% | Oil | Mild irritation at 48 hrs. but absent at 72 hrs; no corneal opacity | Warf 1976, MRID #00001101 |

1/ Washed and Unwashed Eyes

The above data are sufficient to classify registered 15% and 18% RTU products as mild, transitory eye irritants. However, due to the reported results on technical Deet, each of the existing RTU products between 20% and 75% must be tested for eye irritation potential.

#### (2) Pressurized Liquid (PrL)

Adequate primary eye irritation studies were conducted on existing PrL products as shown in Table 14.

Table 14

Primary Eye Irritation of PrL Deet

| Animal | %DEET | Dose | Results | Reference |
|---|---|---|---|---|
| Rabbit[1/] | 15% | 1 second spray | Mild irritation at 72 hrs but absent at 4 days, no corneal opacification | WARF 1975b MRID #00001085 |
| Rabbit[1/] | 15% | 0.1 ml condensate | Mild irritation at 72 hrs, but absent at 4 days; no corneal opacity | WARF 1975b MRID #00001085 Woodward |
| Rabbit[1/] | 30% | 0.1 ml condensate | Mild irritation at 48 hrs; but absent at 72 hrs; no corneal opacity | Durloo and Woodward 1971b MRID #00001082 |
| Rabbit[1/] | 30% | 2 second spray | No irritation at 48 hrs; no corneal opacity | Durloo and Woodward 1971b MRID # 00001082 |

[1/] Washed and Unwashed Eyes

[2/] Unwashed Eyes

The above data are sufficient to classify the tested 15% and 30% PrL products as mild, transitory eye irritants.

However, due to the reported results on technical Deet and the possible eye irritating inert ingredients in some products, each of the existing products must be tested for eye irritation potential.

### (3) Impregnated Material (ImM)

No data were available for the assessment of the eye irritation potential of registered ImM products. However, due to the reported results on technical Deet all ImM products must be tested for eye irritation potential.

### 5. Primary Dermal Irritation (163.81-5)

The minimum data requirement for primary dermal irritation is one test for the manufacturing-use product and one test for each registered product, preferably using the albino rabbit.

a. Technical/Manufacturing-Use Product

Adequate primary dermal irritation studies were conducted as indicated in 15.

Table 15

Primary Dermal Irritation of Technical Deet

| Animal | %m-DEET | Irritation Signs | Toxicity Category | Reference |
|---|---|---|---|---|
| Rabbit | 90-100% | 48 hrs - slight edema<br>48 hrs - slight erythema<br>7 days-clear | IV | Philipps 1972,<br>MRID #<br>05000242 |
| Rabbit[1/] | 95% | 24 hrs - slight erythema<br>48 hrs - slight erythema<br>7 days - clear | IV | U.S. Army, 1979<br>MRID #<br>GS00020269 |

[1/] Abraded and unabraded skin

These studies show that technical Deet is mildly irritating to rabbit skin and corresponds to Toxicity Category IV, indicating a very low primary dermal irritation potential. This information is sufficient to satisfy the data requirement for primary skin irritation for technical Deet.

b. Formulated

(1) Ready-To-Use (RTU)

Adequate primary dermal irritation studies using rabbits were conducted on the registered RTU products shown in Table 16.

Table 16

Primary Dermal Irritation of RTU Deet

| % m-DEET | Results | Toxicity Category | Reference |
|---|---|---|---|
| 15% | No irritation at 72 hrs. using abraded and nonabraded skin. | IV | Davidow 1960<br>MRID # 00001139 |
| 18% | Mild irritation at 72 hrs. using abraded and nonabraded skin. | IV | WARF 1976<br>MRID # 00001101 |

As per the available data on the 15% and 18% RTU products (Toxicity Category IV) and technical Deet (Toxicity Category IV), products between 15% and 25% may be classified as Toxicity Category IV, corresponding to a very low primary dermal irritation potential. However, due to the intended use pattern of Deet and the lack of available data, all products which contain greater than 25% Deet must be tested for primary dermal irritation potential.

(2) Pressurized Liquids (PrL)

The following adequate dermal irritation studies using rabbits were conducted on registered PrL products:

Table 17

Primary Dermal Irritation of PrL Products

| % m-DEET | Results | Toxicity Category | Reference |
|---|---|---|---|
| 15%-15.45% | No irritation at 72 hrs. using abraded and nonabraded skin. | IV | Johnson, 1972;<br>MRID # 00001073<br>WARF, 1975a;<br>MRID # 00001085<br>WARF, 1975b<br>MRID # 00001086 |
| 30% | No irritation at 72 hrs. using abraded and nonabraded skin. | IV | Durloo and Woodward, 1971a<br>MRID #00001081 |

The data show that 15% and 30% PrL products are placed in Toxicity Category IV. Because technical Deet and the 15% and 30% PrL products are placed in Toxicity Category IV, and because the inert ingredients in PrL products are not expeected to increase the primary dermal irritantion potential, all existing PrL products between 12% and 30% concentrations, that do not incorporate from propellants, are placed in Toxicity Category IV. Toxicity Category IV corresponds to a very low primary dermal irritation potential.

(3) Impregnated Material (ImM)

No data were available for the assessment of the primary dermal irritation potential of the registered ImM products. Due to the intended use pattern of Deet and the lack of available data, all ImM products must be tested for primary dermal irritation potential.

6. Dermal Sensitization (163.81-6)

The minimum data requirement for dermal sensitization is a test for the technical product and each registered formulation preferably using the guinea pig.

### a. Technical/Manufacturing-Use

An adequate dermal sensitization study was conducted on guinea pigs (U.S. Army 1979 MRID GS0002026). The animals received 10 appliations of 0.1% technical Deet followed by an insult application after a 2 week rest. No sensitization reaction was noted. These date indicate that technical Deet is not a skin sensitizer.

### b. Formulated

#### (1) Ready-To-Use (RTU)

A supplementary dermal sensitization study was conducted on guinea pigs (Ambrose, 1959 MRID #0001051). The animals received 10 applications of 1 ml of 10% Deet in isopropanol on the dipilated flank. Fifteen days following the last application, the animals received a single insult application. Slight dermal irritation was seen after the 3rd or 4th application; no other reactions were noted. This data suggests that 10% Deet in isopropanol is not a skin sensitizer.

Due to the intended use pattern of Deet and the limited available data, all RTU products must be tested for dermal sensitization.

#### (2) Pressurized Liquid (PrL)

No data were available for the assessment of the dermal sensitization potential of any PrL product. Due to the intended use pattern of Deet, each of the registered PrL products between 12% and 75% and all new products must be tested for dermal sensitization potential.

#### (3) Impregnated Materials (ImM)

No data were available for the assessment of the dermal sensitization potential of any impregnated materials product. Due to the use pattern of Deet, each of the existing ImM products and all new products must be tested for dermal sensitization potential.

## 7. Subchronic Oral Toxicity

The minimum data requirement for testing subchronic oral toxicity is testing in two mammalian species, preferably the dog and rat, using the technical product. Subchronic oral testing is not required for Deet because a significant exposure via the oral route is unlikely. However, the following data were available:

A supplementary 200 day feeding study was conducted on rats (Ambrose, 1959 MRID #00001051). Groups of rats (10 male, 10 female) were fed 0, 0.01, 0.05, 0.1, 0.5, or 1% m-Deet (equivalent to 4.5-10.0, 23.5-45.6, 48.0-92.2, 267.0-474.0, and 531.0-1055.0 mg/kg/day, respectively) in the diet. Male and female rats in the 1% group showed lower weight gains than controls. Average daily food consumption, red cell and plasma cholinesterase values, and hemoglobin counts did not differ from control values for any treatment group.

Control and treated animals had comparable blood cholinesterase values, gross pathology and histopathology. However, there was a statistically significant increase in the organ-to-body weight ratio in the testes, kidneys and liver as indicated in Table 18.

## Table 18

### Organ-to-Body Weight Ratios in Ambrose, 1959 Study

| % Deet | Body weight (gm) | | Organ to body weight ratios | | | | |
|---|---|---|---|---|---|---|---|
| | | | Testes** | Kidneys | | Liver | |
| | Male | Female | Male | Male | Females | Males | Females |
| 0 | 405 | 232 | 0.71+0.03 | 0.55+0.01 | 0.57+0.01 | 2.5+0.07 | 2.7+0.15 |
| 0.01 | 408 | 242 | 0.76+0.03 | 0.57+0.02 | 0.53+0.06 | 2.7+0.10 | 2.5+0.25 |
| 0.05 | 389 | 237 | 0.75+0.01 | 0.59+0.03 | 0.57+0.02 | 2.6+0.09 | 2.6+0.23 |
| 0.10 | 386 | 229 | 0.81+0.02 | 0.57+0.02 | 0.57+0.01 | 2.6+0.10 | 2.3+0.06 |
| 0.50 | 385 | 224 | 0.86+0.05* | 0.99+0.03 | 0.59+0.02 | 3.0+0.11* | 3.0+0.03 |
| 1.00 | 366* | 209* | 0.87+0.02* | 0.62+0.02* | 0.64+0.03* | 3.1+0.14* | 3.6\|0.12* |

*Significant at 5% level.
**The increase in body-weight ratio in the testes suggest a dose-response relationship.

Another supplementary subchronic oral study using technical Deet in dogs was reviewed (Woodward, 1959 MRID # 00001029). Groups of two male and two female beagles were given 85% m-Deet with 10% other isomers) orally by capsule at 0, 0.1, or 0.3 ml/kg/day for 13 weeks. After each daily dose, dogs at the 0.3 ml/kg/day dose level showed signs of slight-to-moderate central nervous system excitation consisting of tremors and hyperactivity. Emesis occurred "from time to time." Animals treated at 0.1 ml/kg/day showed only slight hyperactivity. Hemograms taken throughout the study failed to reveal any consistent changes. At necropsy, there was no evidence of gross pathology associated with the treatment. Organ weights were within normal limits for all animals. Histological studies of all tissues examined (liver, kidney, heart, spleen, ovary, uterus, testis, and adrenal) were within normal limits.

### 8. Subchronic 21-Day Dermal Toxicity (163.82-2)

The minimum data requirement for subchronic 21-day dermal toxicity is one test for the technical chemical, preferably using the albino rabbit. However, a subchronic 21-day dermal test is not required for Deet because the intended use of Deet is purposeful application to the skin and the need for a 90-day dermal toxicity test precludes the requirement for a 21-day dermal toxicity test.

### 9. Subchronic 90-Day Dermal Toxicity (163.82-3)

The minimum data requirement for subchronic 90-day dermal toxicity is one test for the technical chemical, preferably using the albino rabbit. The subchronic 90-day dermal toxicity is required because pesticidal use of Deet involves purposeful application to the skin.

Two supplementary subchronic dermal toxicity tests were conducted on rabbits (Ambrose, 1959 MRID #00001051 and Woodard, 1959 MRID # 00001029). These were as follows:

1. The application of Deet (85-100% m-Deet) to intact rabbit skin for 90 days at a dose of 1 ml/kg/day produced moderate skin irritation but no effect on weight, behavior, or mortality (Ambrose, 1959 MRID #00001051). Although these data suggest no systemic effects of technical Deet, the lack of

pathologic examination and reporting of clinical parameters precludes the use of this study.

2. In the other study, rabbits (six per dose) dermally dosed the 0, 0.75, 1.50 and 3.0 ml/kg/day of Deet (85% m-Deet, 10% Deet isomers) for 90 days showed mild dermal irritation (0.75 ml/kg/day) to severe dermal irritation (3.0 ml/kg/day) (Woodard, 1959 MRID # 00001029). In addition, increased kidney weights and marked histopathological changes were noted in the intermediate dose animals (1.5 ml/kg/day). Two rabbits dosed at 1.5 ml/kg/day died, and all the rabbits at the high dose (3.0 ml/kg/day) dies. However, the lack of clinical data (e.g. growth curves, blood chemistries, etc.) and the lack of data on individual animal preclude the use of this study.

The available information is not sufficient to satisfy the requirement on subchronic 90-day dermal toxicity; additional testing is required.

### 10. Subchronic Inhalation Toxicity (163.82-4)

The minimum data requirement for subchronic inhalation is one test for the technical formulation, preferably using the laboratory rat. The registered end uses of Deet could result in repeated inhalation exposure.

A supplementary subchronic inhalation study was conducted on rats (Ambrose, 1959 MRID #00001051). Rats exposed to air "saturated" with Deet in an inhalation chamber for 8 hours a day, 5 days a week, for 7 weeks showed no effect on behavior, mortality, of histopathology. Although the data suggest that no adverse effects resulted from subchronic inhalation exposure, this study is not sufficient to meet data requirements for subchronic inhalation because actual doses were not reported, and incomplete pathology was reported.

An adequate subchronic inhalation study was conducted on rats (male and female) and Beagle dogs (male and female) (U.S. Army, 1979 MRID #GS 0002034). The animals were exposed to aerosol concentrations of 0 (room air), 2.5, 7.5, or 15.0 mg/l of Deet for 6 hours per day, 5 days per week for 13 weeks. The lowest effect level (LEL) for rats is 15.0 mg/l (transient red exudate around the eyes and nose were noted); the no effect level is 7.5 mg/l. In addition, an increase in sperm with abnormal morphology was noted in rats at the 15.0 mg/l dose. However, this effect is evidence that mutagenicity and reproductive testing are necessary.

### 11. Chronic Feeding/Dermal Toxicity (163.83-1)

The minimum data requirement for chronic feeding/dermal toxicity is one test for the technical chemical, preferably using the laboratory rat. A chronic dermal study is required because pesticidal use of Deet could result in application to the skin for significant periods of time. The chronic dermal toxicity study would be conducted as a part of a chronic feeding study.

### 12. Oncogenicity (163.83-2)

The minimum data requirement for oncogenicity is testing in two mammalian species, perferably the rat and mouse, using the technical chemical.

A screening bioassay was conducted on rabbits and mice (Stenbaeck, 1977 MRID# 05000045). Groups of 50 females mice or 5 rabbits (sex distribution unspecified) received dermal applications of 10%, 50% or 100% Deet in ethanol.

The positive control used was DMBA. This study resulted in no statistically significant results, and is also not adequate to satisfy testing requirements for the following reasons:

The mouse experiment was conducted on only female mice with limited histological examinations performed (only grossly observed lesions were examined microscopically and the extent of the examination was not descirbed); no data were provided on individual animals; no clinical data were reported; and there was; no indication if the maximum tolerated dose was administered.

The Rabbit study was conducted using an Insufficient number of animals; no data were provided on individuals animals; no pathology report was provided for tumor types; no clinical data were reported; there was no; no indication if the maximum tolerated dose was administered; and there were early and abrupt deaths (40% at the 10% and 100% dose levels at 80 weeks; 100% at 10%, 50% amd 100% dose levels at 90 weeks), causing concern about the conduct of the study.

Additional oncogenic testing is required in two mammalian species.

### 13. Teratology (163.83-3)

The minimum data requirement for teratology is testing in two mammalian species using the technical chemical.

An adequate dermal teratology study (U.S. Army, 1980 MRID #GS0002036) was conducted on rabbits. Groups of 20 pregnant rabbits received daily dermal applications of 0, 50, 100, 500, 1000, or 5000 mg Deet/kg/day in ethanol (vehicle control) on shaved backs from day 0 through day 29 of gestation. Precautions were taken to prevent the animals from licking treated skin and skin was not washed between treatments. There were no significant differences between control and treated animals with respect to the fertility index, number of implantations per animal, or number of fetuses per animal. In addition, treatment did not change fetal weight, fetal length or placental weights and no increases in the incidence of skeletal or soft tissue anomalies were observed in treated groups when compared with untreated controls. This study demonstrated that Deet has no teratogenic or embryotoxic effects in rabbits exposed dermally to technical Deet.

An additional supplementary teratology study (Grahwitt, 1977 MRID # 00001063) was conducted on rats. Groups of 20 pregnant rats were daily administered 10 ml of peanut oil containing 0, 8, 20 or 80 mg/kg/Deet by gavage from day 5 through day 15 of gestation. No significant differences were reported between control and treated mothers with respect to fertility, fetuses per liter, fetal weight or fetal survival. However, the study did show decreases in number of implantation sites per dam and number of fetuses per animal. In addition, a related increase was observed in the number of resorptions per dam (see summary table below).

## Table 19

### Summary of Results
### in
### U.S Army (1980) Teratology Study

| Parameter | Control | 8mg/kg | 20mg/kg | 80mg/kg |
|---|---|---|---|---|
| Implantations/dam | 10.65 | 10.00 | 10.21 | 9.10 |
| Fetuses/dam | 10.45 | 9.25 | 9.37 | 7.70 |
| % Live fetuses | 100 | 100 | 99.44 | 100 |
| Fetuses/litter | 10.45 | 9.74 | 9.89 | 9.10 |
| Resorption/dam | 0.20 | 0.75 | 0.84 | 1.43 |

These summary data are somewhat misleading because two animals in the high dose group had low body weights and had 8 resorption sites each. A third animal, which had 5 resorption sites, delivered viable fetuses and its body weight was comparable to control animals. These 3 animals represent 75% of the total number of resorptions for this group. In addition, the number of implantations per animal in the high dose group was lower than that in control animal (9.10 and 10.65, respectively). These results are not compound related because Deet dosing began 3 days after implantation normally occurs in rats.

These data suggest the possibility of impaired maternal health prior to the administration of Deet; therefore, the significance of the suggested embryotoxicity at 80 mg/kg/day cannot be determined. However, the suggested embryotoxic effect is evidence that additional teratology testing is required in the same species.

Another teratogenicity study was reviewed and deemed insufficient to assess potential teratogenicity (Gleiberman, 1975 MRID #05000007). There are insufficient details reported to assess the protocol and no characterization of the chemical administered was reported in the study.

### 14. Reproduction (163.83-4)

The minimum data requirement for measuring reproductive indices is one test in the laboratory rat lasting two generations using the technical formulation.

An inadequate study was provided for assessment of the reproductive toxicity of Deet (Gleiberman, S., 1976 MRID # 05000008). There are insufficient details reported to assess the validity of the study and no characterization of the chemical administered was reported.

Although this study is not suitable to meet data requirements for reproductive testing it does suggest potential sperm abnormality. The authors report that by "the special function-morphological examination of spermatozoa, both motility time and the number of pathological forms (deformation, absence of tail or head, thickening of middle piece, etc.) differed reliably from similar indices in control animals." Without additional specific information the Agency cannot interpret the significance or the validity of this finding.

Additional reproductive testing is required.

### 15. Mutagenicity (163.84-1 through-4)

Although the Agency's mutagenic testing requirements are not final, refer to the "Proposed Guidelines" (43 FR No. 163, August 22, 1978) for information concerning the types of studies the Agency is considering.

The following studies are representative and are likely to be required:

1) Microbial point mutation
2) Mammalian in vitro point mutation
3) In vitro or in vivo cytogenetics or one of the following: heritable translocation or dominant lethal
4) Primary DNA damage, e.g. sister chromatid exchange or inscheduled DNA synthesis.

Mutagenic studies are required because pesticidal use of Deet involves purposeful application to the skin.

Several supplementary mutagenicity studies were reviewed for this Standard. In one study (Litton Bionetics, Inc. 1977 MRID#GS0002036), Deet did not induce reverse mutations in S-9 activated or inactivated S. typhimurium TA-1535, 1537, 1538, 1598 and 15100, and did not induce gene conversions in unactivated S. cerevisia D4. No conclusion could be drawn regarding the S-9 activation system in S. cerevisia D4 in the same study due to uncertainties in the preincubation suspension technique.

A supplementary dominant lethal study was conducted using three groups of ten male lCR/Ha Swiss mice (U.S. Army, 1979, GS0002021). The concurrent control group was administered a single dose by gavage of 5 mg/kg corn oil, the positive control group was administered 10 mg/kg TEM, and the experimental group was administered 600 mg/kg Deet. The study resulted in no dominant lethal effects, however, a statistically significant ($p < 0.02$) reduction of a plants was noted in pregnant females. This effect is evidence that a reproductive study is necessary. Although this study was generally conducted adequately, the maximum tolerated dose was not administered; therefore, the study is not sufficient to meet the data requirement for mutagenicity.

### 16. Metabolism in Laboratory Animals (163.85-1)

The minimum data requirement for metabolism is a single dose using the analytically pure grade of the active ingredient in the radioactively labelled form. A metabolism study is required using technical Deet because oncogenicity and chronic studies are required.

Metabolism studies showing excretion levels and absorption rates are summarized in Table 20. Tissue distribution studies are summarized in Table 21 and several studies conducted during pregnancy are summarized in Table 22.

The studies on animals suggest that m-Deet is rapidly absorbed and excreted in the urine. Distribution studies show the liver, kidney, bladder and lacrimal glands are the preferred organs, however excretion rates are so high (98%) that there is no evidence of bio accumulation. In addition, there is suggestive evidence that m-Deet does cross the placenta in mice (Bloomquist, 1975 MRID # 05000001) and rabbits (U.S. Army, 1979 GS0002023); however, there is no accumulation of Deet in any fetal organ indicating rapid fetal excretion.

Additional data is needed to identify metabolites of Deet an their potential bioaccumulation.

Table 20

Metabolism in Laboratory Animals

| Animal | Dose | Route | % Absorbed | Excretion (Where excreted/Time) | Reference |
|---|---|---|---|---|---|
| Guinea Pigs | 50 mg/kg<br>$C^{14}$ Deet | Dermal | 20-50% | 80% urine/24hrs.<br>1% feces/8 days | Schmidt, (1959) MRID |
| Guinea Pigs | 51 mg/kg<br>$C^{14}$ Deet | Dermal | NS | 70-80% urine/24<br>1% feces/un-speciied | Kingscote, (1959) MRID #05000271 |
| Mice | 15mg/kg<br>$C^{14}$ Deet | Dermal | NS | 13% urine/2,5hrs.<br>34% urine/48hrs. | Bloomquist (1977) MRID #05000002 |
| Mice | 5uCi /10gm<br>$C^{14}$ Deet | I.V. | NS | 95.6% urine/8hrs.<br>97.3% urine/40 hrs.<br>0.6% feces/48hrs. | Bloomquist (1975) MRID 05000001 |
| Rats | 100mg/kg<br>$C^{14}$ Deet | Dermal | NS | 42% urine/6hrs.<br>68% urine/24hrs. | Lure et al. (1978) MRID #05000020 |
| Rat/Male | NS | Dermal | 43% | NS | U.S. Army (1969) MRID #GS0002034 |
| Rat/Female | NS | Dermal | 32% | NS | U.S. Army (1979) MRID #GS0002034 |
| Rabbit | NS | Dermal | 36% | NS | U.S. Army (1979) MRID #GS0002024 |
| Dog | NS | Dermal | 30% | NS | U.S. Army (1979) MRID #GS0002034 |

NS = Not specified

## Table 21

## Tissue Distribution Studies

| Animal | Dose | Route | Tissue Distribution/Time After Dosing | Referance |
|---|---|---|---|---|
| Mice | 15mg/kg | Dermal | 1) Lacrimal Gland, liver, Kidney nasal mucosa/2 hrs.<br>2) Skin at application area, traces in Bladder/6 days<br>3) Skin at application area/36 days. | Bloomquist, (1977) MRID #05000002 |
| Mice | 5u Ci/ 10 gm | I.V. | 1) Lacrimal gland, liver, kidney, small intestine (high level); Adipose, central nervous system (low level)/5 min.<br>2) Lacrimal gland, renel marrow, nasal mucosa, bladder, small intestine/1 hr.<br>3) Lacrimal gland, liver, nasal mucosa, bladder, intestine (low level)/24 hrs.<br>4) No trace of radioactivity at 4 days. | Bloomquist, (1975) MRID #05000001 |

## Table 22

## Tissue Distribution Studies in Pregnant Animals

| Animal | Gestation Time | Dose | Route | Time/Result | Reference |
|---|---|---|---|---|---|
| Mice | "Advances Dermal Pregnancy" | 5uCi/ 10G | I-V | (1) 20 minutes/fetal bone marrow, urinary bladder, gastric mucosa lens showed "some accumulation"; average low concentration in the fetus was "very low."<br>(2) 4 hours/no accumulation in any fetal organ. | Bloomquist (1977) MRID #05000002<br>Bloomquist, (1975) MRID #05000001 |
| Rabbit | Day-1 through Day-29 | ? | Dermal | No detectable radioactivity above background was observed in any fetus. | U.S. Army (1979) MRID # GS0002034 |
| Rabbit | Day-15 | ? | Dermal | Radioactivity was "lower" in fetuses than comparable maternal specimens | U.S. Army (1979) MRID #GS0002034 |

## 17. Clinical Trials —Metabolism and Pharmacodynamics

Although comprehensive metabolic and pharmacodynamic studies of the absorption, fate and excretion of Deet and its metabolites in human beings are not available, a few studies have measured rates of evaporation, dermal absorption, and urinary excretion.

Spencer et al. (1979, MRID #05007487) investigated the rate of evaporation of Deet after dermal application. The average total loss from human skin by evaporation, wiping, and stripping of the stratum corneum was 49% of the applied dose. This also suggests that some of the applied Deet that was not recovered penetrated the skin.

Feldman and Maibach (1970, MRID # 05003588) investigated the dermal absorption and excretion of radiolabeled Deet in four human volunteers. A total of 52 ug of Deet was applied once to the ventral forearm. The total average urinary excretion at 24 hours was 13.3% of the dose, at 48 hours it was 15.3%, and at 120 hours it was 16.7%.

Blomquist and Thorsell (1977, MRID # 05000002) applied 250 uCi of 14 C-Deet in 0.03 ml (0.12 mg/kg of body weight) of a 20% ethanol solution to the forearm of one woman volunteer. The experiment was performed twice, but the time interval between the two experiments was not specified. The amount of radioactivity recovered in the urine during 48 hours was 5.5% of the first dose applied and 3.8% of the second. Washing of the treated skin area 8 hours after each application resulted in the recovery of 8% of the first dose and 15% of the second.

Markina and Yatsenko (1971, MRID # 05000599) investigated the dermal absorption of different formulations of Deet (20-40% active ingredient) in 15 persons and found that only trace amounts of Deet were detected in the urine when silcone or cellulose acetobutyrate additives were added to the Deet cream or lotion. No toxicity was reported after 30 days of daily application of the lotion. Medical examination revealed no effects.

These studies suggest that the dermal absorption of Deet is rapid but that excretion rates are variable. The number of subjects in these studies, however, is too small to allow more than a tentative conclusion regarding excretion rates. Pharmacodynamic studies also suggest that a considerable amount (15% or more) of the applied dose remains on the skin for at least 8 hours after application.

## 18. Dermal Irritation and Sensitization in Humans

Technical Deet (purity unspecified) in ethanol was not irritating to human skin when applied as a single dose (Phillips et al., 1972 MRID # 05000242). When applied to occluded human skin daily for 21 consecutive days as 1, 10, 20, 30, 60, or 80% ethanol solutions, mean scores over the 21-day period on a scale of 0-4 were 0.43, 0.13-1.13, 2.9, 2.4, 2.3, and 1.0, respectively. No irritation was observed when 100% technical grade Deet or a 50% ethanol solution was applied daily for 21 consecutive days to unoccluded human skin.

Ambrose (1959 MRID #00001051) applied a 50% solution of Deet to the arms and faces of five human volunteers once a day for 5 days. No irritation of the arms was observed. However, after the third application some desquamation around the nose was apparent in all subjects. No further symptoms were noted after application of the solution was discontinued.

Lamberg and Mulrennan (1969 MRID # 05002308) applied patches moistened with 75% Deet (as a liquid in 25% ethanol or as a spray in 25% dichlorodifluoromethane) to the anticubital fossae of 77 men. This resulted in burns or in skin reactions of either bullar or erosions resembling abrasions in 48% of the men. These reactions led to necrosis and scarring in some of the subjects. However, when patches were applied to the upper inner part of the arm of 62 of these men, there were no skin reations.

Vos (1972 MRID #00001093) patch-tested 52 adults with 15% Deet liquid three times a week for 9 weeks. After a 2-week rest period, a challenge patch was applied. Because only one of the subject developed a slight erythema after removal of the challenge patch, it was concluded that Deet is not a skin sensitizer.

Blau and Kanof (1961 MRID #00001182) applied blotting paper impregnated with a spray containing 7.5% Deet and 1.5% isobutyl salicyl cinnamate (Revlon Sun Bath) to the backs of 402 women. After 48 hours, the patches were removed and the skin was observed for signs of irritation. Of the 402 subjects, 9 showed a "minimal plus-minus" reaction; the rest were negative.

These studies show that Deet is not usually a dermal irritant or a skin sensitizer. However, in selected individuals and under special circumstances Deet can cause extensive skin reactions.

### 19. Case Reports

Maibach and Johnson (1975 05000021) reported that a 35-year-old woman developed red raised lesions after application of an insect repellent containing an unspecified amount of Deet. She was given open patch tests for sensitvity to several insecticides but only pure samples of Deet produced a wheal and flare reaction, which is considered contact urticaria or immediate-type hypersensitivity. Further investigation revealed that this response could be passively transferred, indicating that the contact urticaria to Deet was caused by an immunologic response.

Gryboski et al. (1961 MRID #05000328) described the case of a 3.5-year-old girl who, after exposure over a 2-week period to 180 ml of 15% Deet spray, experienced a toxic encephalopathy including disorientation, staggering gait, slurred speech, and episodes of crying out, stiffening into a sitting position, extending the extremities, flexing the fingers, and dorsiflexing the toes. She recovered after 4 days, and since that time she has reportedly been well. All clinical examinations to discover other etiologic factors, including family history, virology, bacteriology, and lead testing, proved to be negative; however, tests to confirm that Deet was the causative agent in this episode were not performed.

Zadjoff (1979 MRID #05007489) reported two additional cases of toxic encephalopathy in children after exposure to Deet. A 5-year-old girl sprayed nightly for 3 months with Mylol (containing 10% Deet) experienced a toxic encephalopathy, including slurred speech ataxia, and generalized convulsions. She died 24 days after hospitalization. The brain showed generalized edema with congestion of the meninges, and the cerebral blood vessels showed swelling of endothelial cells. In another case, an 18-month-old girl ingested an unknown amount of Mylel liquid containing 10% deet. The next day she became irritable, displayed bizarre movements, and had depressed muscle stretch reflexes. She improved somewhat during 6 weeks of hospitalization. After 6 weeks, her head control was not yet normal, and her tendon reflexes remained depressed, but the case was not followed up.

Other reports of toxicity related to Deet exposure are discussed in Rabinovich (1966 MRID #05000693) and the Pesticide Incident Monitoring System Report Number 121 (PIMS 1978).

Rabinovich (1966 MRID #05000693) conducted a field trial on 600 lumbermen who used a 60% Deet solution and reported occasional contact dermatitis, aggravation of preexisting acne, conjunctivitis, and burning eyes.

Pesticide Incident Monitoring System Report Number 121 (PIMS 1978) lists 45 cases of Deet exposure found in the files of the Pesticide Incident Monitoring System for the period covering 1966 to December 1978. For 29 of these cases, data on the incident and sequelae were insufficient to draw any conclusions relating to the toxicity of Deet. The remaining cases included 10 incidents of temporary eye irritation; 6 cases of skin reactions involving blisters, rashes, irritation, and hives; and 1 case of a generalized allergic response requiring hospitalization.

The cited literature indicates that the general toxicity of Deet is low; that local skin reactions are infrequent, but can be severe depending on the area of application and on individual response; and the eye irritation, although slight and temporary, occurs frequently. There is inadequate information to judge potential effects in persons with preexisting allergic conditions or to determine if other populations, for example, children and pregnant women are at risk.

## 20. Emergency Treatment

No information has been submitted on emergency treatment of Deet intoxication.

## 21. Special Testing—Sperm Count, Spermhead Morphology, Sperm Viability

A valid morphology, viability and sperm count was conducted in rats (Litton Bionetics 1980 MRID #GS0002036). Groups of 80 male sprague-Dawley rats were dermally administered doses 0, 100, 300 or 1000 mg/kg/day of Deet for 5 days each week for 9 weeks.

There were no significant differences between treated and control rats with respect to mean body weights and food consumption (no statistical tests were considered necessary by the authors). Histological examination of the testes of rats in the high dose and control groups revealed no lesions nor the occurence of compund related hyposnermatogenesis. The appearance of liver and kidneys in treated rats was normal at necropsy. The only organ weights affected were those of liver and kidneys in the high dose rats at the first kill (no effect on testes weight was as shown in Table 23.

Table 23

Organ Weight Results in Litton (1980) Sperm Study

| Dose (mg/kg) | Mean liver wt. (g) | % Body wt. | Mean Kidney wt. (g) | % body wt. |
|---|---|---|---|---|
| 0 | 19.2550 | 4.4521 | 3.5100 | 0.8154 |
| 1000 | 19.8400 | 4.7427 | 4.2050 | 1.0062* |

* significantly different from controls
(P is less than 0.05) using the
students +-test; no data from low
and misdosed groups reported.

There were no compund-related effects on sperm count, sperm head morphology, orsperm viability of treated male rats at repeated dermal doses up to 1000 mg/kg/day.

### 22. Age-Related Dermal Absorption Studies

The Agency is concerned with the possible age related differences in dermal absorption of Deet because Deet is used on children. Therefore, a dermal absorption study is required in weanling and young adult rats. Rats are chosen as the experimental animal because most of the toxicology and metabolism data will have been performed in rats, thus permitting correlation of data.

Table 24

Toxicity Category Indicators

| Hazard Indicators | Toxicity Categories<br>I | <br>II | <br>III | <br>IV |
|---|---|---|---|---|
| Oral $LD_{50}$ | Up to and including 50 mg/kg | From 50-500 mg/kg | From 500-5000 mg/kg | Greater than 5000 mg/kg |
| Inhalation $LD_{50}$ | Up to and including 0.2 mg/liter | From 0.2-2 mg/liter | From 2-20 mg/liter | Greater than 20 mg/liter |
| Dermal $LD_{50}$ | Up to and including 200 mg/kg | From 200-2000 mg/kg | From 2,000-20,000 mg/kg | Greater than 20,000 mg/kg |
| Skin Effects | Corrosive | Severe irritation at 72 hours | Moderate irritation at 72 hours | Mild or slight irritation at 72 hours or no effects |

Table 24 A

Eye Irritation Toxicity

Indicators for Formulated Deet Products

| Acceptable for Domestic Use | Not Acceptable for Domestic Use |
|---|---|
| No corneal opacity; irritation reversible within 7 days | Corrosive; any corneal opacity; irritation persisting for 7 days |

# VI. ECOLOGICAL EFFECTS

## A. Disciplinary Review

### 1. Ecological Effects Profile and Hazard Assessment

Subpart E, "Hazard Evaluation: Wildlife and Aquatic Organisms," of the" Proposed Guidelines, Registration of Pesticides in the United States", published in the Federal Register on July 10, 1978, describes the fish and wildlife data required by the Agency to assess the hazards of pesticides to nontarget organisms and to provide for adequate precautionary labeling (43 FR 132, Part 163.70 through .72).

Formulated Deet is neither intended for application to outdoor sites, nor registered for such use; consequently, formulated Deet will not be reviewed in this Chapter. However, an understanding of technical Deet's toxicity to fish, aquatic invertebrates and waterfowl is fundamental to the development of appropriate clean-up measures in the event of a chemical spill into lakes and streams. The Agency's concern in this regard is supported by data indicating that a high volume of technical Deet is manufactured in the U.S.; manufacturers are located in diverse areas of the country; and there are a large number of formulators (over 100). The ecological effects review in this Chapter relates only to fish, aquatic invertebrates and waterfowl, and not to upland game birds or other non-aquatic wildlife, because the latter are not expected to experience effects of aquatic spills.

In general, the available data were insufficient to support an assessment of technical Deet's ecological effects. The only valid study, (McCann, 1972, MRID # 00001026) provided data which demonstrate that technical Deet has a slight acute toxicity to coldwater fish.

### 2. Data Gaps

The following gaps in the Ecological Effects data base must be filled to adequately support the continued registration of technical Deet. After each requirement is listed the section in the Proposed Guidelines of July 10, 1978 (43 FR 132, Part 163.70-.72) which describes the test in detail. These data requirements are also listed in Table 1, Chapter 2.

| | |
|---|---|
| 1. Avian single-dose $LD_{50}$ (wild waterfowl, preferably mallard duck) | 163.71-1 |
| 2. Fish 96-hour $LC_{50}$ for warmwater species | 163.72-2 |
| 3. Aquatic invertebrate acute $LC_{50}$ | 163.72-2 |

### 3. Required Labeling

There are no ecological effects labeling requirements for technical or formulated Deet.

## B. Topical Discussions

The data requirements listed below correspond to the sections in the "Proposed Guidelines for Registration of Pesticides in the United States", published in the Federal Register of July 10, 1978, which explain the data the Agency requires to adequately assess the hazards of technical Deet to fish and wildlife.

| Data Requirements | Guidelines Section |
|---|---|
| Birds (wild waterfowl only) | 163.71-1 |
| Fish (cold and warmwater species) | 163.72-1 |
| Aquatic Invertebrates | 163.72-2 |

Birds (wild waterfowl)

No valid studies on the effects of single oral doses of Deet to wild waterfowl were submitted.

Because data were not available, no conclusion can be drawn about the toxicity of Deet to wild waterfowl; this constitutes a data gap.

Fish

One valid study concerning the acute toxicity of technical Deet (95% a.i.) to fish (McCann, 1972, MRID #00001026) provided data on coldwater species. McCann reported a 24-hour LC-50 of 125 ppm and a 96-hour LC-50 of 172 ppm for rainbow trout. These results are sufficient to characterize Deet as slightly toxic to coldwater fish.

No data concerning the acute toxicity of technical Deet to warmwater fish were submitted; this constitutes a data gap.

Aquatic Invertebrates

No studies concerning the acute toxicity of Deet to aquatic invertebrates were submitted; this constitutes a data gap.

# VII. EFFICACY

## A. Introduction

This chapter deals with the efficacy of Deet when utilized as the single active ingredient in an insect repellent product. The review of Deet data and the identification of data gaps is limited to efficacy data only as it relates to public health applications. The Agency has provided for the waiver of efficacy data submission as a part of the registration process in all other instances (44 FR 2793; May 11, 1979).

The pest species found on registered Deet labels that fall within the Agency's area of public health concern are as follows:

Biting flies (black fly, sand fly, horse fly and Ceratopogonid species)
Chiggers
Deerflies
Fleas
Leeches
Mosquitoes
Stableflies
Ticks

The Agency reviewed all pertinent studies. Many papers, while providing valid and useful data, were not considered because the data related to formulations containing more than one active ingredient. The Agency did not reject any data on the basis of test methodology, but considered that all data would contribute to the assessment of efficacy (See Appendix I.).

## B. Efficacy Assessment

### 1. Factors Influencing Efficacy

Several factors appear to influence the efficacy of Deet. Major factors are environmental conditions, extent of absorption and elimination, type of repellent formulation, and avidity of the test species. One or more of these conditions always influences the duration of Deet's protection.

Environmental conditions, such as temperature and wind velocity, alter Deet activity. Deet efficacy is reduced by increased perspiration rate, although not by elevated temperature.

Although data generated by Smith (Smith *et al.*, 1963, MRID# 05000300) were inconsistent, they suggest that perspiring might reduce Deet protection time against the mosquito, *Aedes aegypti*. Wind velocity also influences Deet protection time. Khan (Khan et al. 1973 MRID 05000193) demonstrated that wind velocities of 192 meters per minute decreased efficacy on the order of 66% when compared to data collected in a room with "normal" air exchange rates.

The duration of repellent activity is influenced by washoff, abrasion from the treated surface, and absorption. Water, from either rainfall or perspiration, decreases the efficacy of Deet. Gouch (Gouch *et al*, 1971, MRID# 05000214) reported that netting treated with 0.25 gram active ingredient of Deet per gram of netting was effective in repelling 90% of a population of *Aedes taeniorhychus* mosquitoes for a period of 54 days. Approximately 0.3 inches of precipitation, however, reduced the effectiveness to less than 90% when measured over the same period. Similarly, Schiefer (Schiefer et al., 1976, MRID 05000223) noted a reduction in the overall efficacy in response to rainfall. Deet's effectiveness has been reported to be reduced by loss through cutaneous absorption (Maibach et al. 1974, MRID 0500116). Since Deet is highly lipophilic, it is reasonable to assume that loss by absorption would be accelerated when lotions, creams, and stick-type formulations are applied. Much data has been reviewed about the formulation dependency of Deet activity; the Agency has considered only the effect of the range of percent active ingredient in its target pest assessment.

Given the absence of data relating to the upper limit of Deet efficacy based on percent active ingredient, the Agency will not prescibe the maximum level of Deet allowable in any formulation. However, the Agency will consider toxicology hazards of all formulations, balancing the risks against the benefits of any formulation for which a suspected hazard exists.

Although overall efficacy of Deet can also be seriously reduced by inadvertent abrasion from the skin, there are data that suggest the Deet can protect surrounding untreated skin up to 4-8 cm. from the treated area (Kahn and Maibach 1972, MRID 00001163).

### 2. Use Sites

#### a. Human Skin

The data clearly indicate that Deet products which contain greater than 10% active ingredient are efficacious for use on human skin. Any performance claims made must fall within the general parameters prescribed in each of the pest-specific discussions in Part 3 of this section.

#### b. Clothing

To repel fleas and chiggers, the product must be applied to clothing in order to work statisfactorily. In the case of other pests, (e.g. black flies, mosquitoes, etc.), clothing treatment may be advisable. The Agency, therefore, recognizes clothing treatment efficacy. The Agency also recognizes the potential utility of specialty formulations for this use. The Agency will consider the specialty products supported under this standard. Any performance claims made must fall within the general parameters prescribed in each of the pest-specific discussions under Target Pests below.

#### c. Tents and Bedrolls

A limited number of Deet products bear claims for treatment of tents and bedrolls. The Agency has very little data directly related to this use (e.g., netting and general cloth treatment). However, through extrapolation from these data, the Agency considers applications for use on tents and bedrolls to be supported under this standard. Claims made for such applications must fall within the general parameters prescribed in each of the following pest-specific discussions.

#### d. Treatment of Screens in Domestic Dwellings

As in the preceeding case, a limited number of Deet formulations bear claims for the treatment of screens. Again, while no data directly related to screens are available, the Agency will extrapolate from the data available for netting treatment. Screen treatments may not be claimed for all pests, however. Claims for screen application may only be made for mosquitoes, ceratopognoid species and black flies. Any claims made for these pests must fall within the parameters prescribed in each of the following pest-specific discussions.

### e. Outdoor Mist Application

A single registered Deet product is claimed to be efficacious for outdoor mist application on and around lawn chairs, picnic tables, boats and other areas where repellency might be desired. The Agency has been unable to relate these sites or this method of application to available data. Since available data show that Deet is effective only as much as 4 to 8 centimeters out from a treated surface, (Kahn and Maibach 1972, MRID 00001163), the Agency contends that such applications are ineffective. These claims will not be supported under this standard. Registrants desiring to make these claims will be required to submit supporting efficacy data.

## 3. Target Pests

### a. Black flies

Deet, applied in formulations where it is the sole active ingredient, has been demonstrated effective in repelling several Simulidae species for periods of 2.6 to 10 hours. Formulations for which acceptable data have been reviewed range from 15 to 65% active ingredient. Although the available data are inconclusive in establishing the low dose range at which Deet might prove effective, they do indicate a distinct dose related reponse. A 15% Deet formulation, applied at 1 gram per 645 $cm^2$ was reported to effectively repel S. venustum for a period of 2.6 hours (S.C. Johnson and Son, Inc. 1974, MRID 00001095). Formulations of 50 and 60% were effective in extending the protection time to 10 and 10.6 hours respectively (Garnett and Lomax 1973, MRID 00001137).

### b. Ceratopogonidae (Biting midges, sandflies)

Formulations containing a minimum of 15% Deet active ingredient, have been shown to be effective against the Ceratopogonidae. The dose-effect relationship is more obscure for this target pest, probably as a result of the somewhat smaller data base. Deet formulations ranging from 15 to 50% have been shown to protect against Ceratopogonidae species for periods of 3.0 to 7.0 hours.

### c. Horse flies

There is an absence of data relating to the efficacy of Deet on horse fly species. Claims for horse flies, therefore, are not supported by this Standard. Any registrant desiring to add claims for horse flies must submit appropriate efficacy data.

### d. Chiggers

All available data on Deet efficacy against chiggers were derived from laboratory studies involving cloth treatment. Although all the studies were laboratory tests, the results were so consistent that the Agency considers the data base adequate. Deet activity against chiggers primarily results from contact toxicity rather than repellency. Studies indicate that Deet, applied to cloth test surfaces, often exhibits toxic action in less than 60 seconds after application (USDA 1959, MRID 00001165); (Gertler 1962, MRID 00001018). In tests conducted against Trombicula splendons, one of the two most frequently encountered chiggers species within the United States, cloth treated at 1 gram per square foot remained effective for a period of 15 days (Kochhar 1974, MRID 05000150); (Gilbert 1957, MRID 05000237). $_2$Trombicula alfreddugesi, was also killed at an application rate of 2 gm/ft$^2$ (Gerberg 1966, MRID 0001171).

The data base for technical Deet is adequate, even when restricted only to proof of Deet's toxicity to chigger species. It is also clear that Deet-impregnated cloth can remain effective over a period of several days.

### e. Deerflies

The data reviewed have indicated that the deerfly is the least susceptible of all dipteran species to Deet products. Formulations ranging from 12.5 to 75% have been evaluated. The duration of acceptable repellency has ranged from 1 to 8 hours, with an average of 1 to 2 hours. There are distinct differences occuring between deerfly species. Schreck (Schreck et al. 1976 MRID 05002304) noted differences in Deet protection time when tested against Chryspos atlanticus and C. flavidus. C. flavidus appeared more responsive to Deet; a 12.5% formulation afforded 135 minutes of protection. C. atlanticus however, was repelled for only 13 to 32 minutes by a formulation containing 50% active Deet. Similar results were obtained in an additional study utilizing C. atlanticus as the test subject (S.C. Johnson and Son, Inc. 1974 MRID 00001095). In this study, Deet provided adequate repellent activity for 36 and 27 minutes for skin-applied formulations containing 10 and 15% Deet respectively. Available data establish that the Deet repels deerflies. The data also indicate that protection time varies considerably due to sensitivity of different species.

### f. Fleas

Few studies are available on the efficacy of Deet products on fleas. Those studies which have been located and reviewed deal primarily with Xenopsylla and Ceratophyllus species. In laboratory studies (Kasafutdiner 1971, MRID 05000077), Deet applied to cloth at 40 grams of active ingredient per square meter provided 100% repellency against Ceratophyllus tesquorum for a period of 30 days. In field tests with humans (Fristane et al. 1970 MRID 05000589), a 40% Deet formulation applied to footwear and overalls at a rate of 80 grams of active ingredient per square meter afforded protection for 1-2 months against Xenopsylla gerbilli fleas. Dremova (Dremova et al. 1977, MRID 05000086) conducted laboratory trials and found that Deet treated cloth (20 grams active ingredient per square meter) provided over 90% repellency of Xenopsylls cheopis for a period of 15 days. In another laboratory study, Zolotarev and Stavroskaya (Zolotarev and Stavroskaya 1960, MRID 05004738) found the p-isomer of Deet to be the most effective in repelling a mixed population of fleas. The m-isomer, while somewhat less effective that the p-isomer, was effective for periods of 2 to 35 days; the variation in the protection period being largely a function of application rate. Despite the relatively small data base, the available data are adequate in establishing Deet repellency toward fleas for products containing 10% or more active ingredient of Deet. There is only a slight variation between the different species' response to Deet. There are no data on formulations containing 10% active ingredient or less. The Zolotarev paper clearly establishes a dose/response relationship.

### g. Leeches

Field and laboratory data indicate that Deet provides short-term protection against Haemadipsa and Hirudo leeches. Saxena et al. (Saxena, et al. 1969, MRID 05003639) conducted field tests to determine the efficacy of Deet against the terrestrial leech Haemadipsa sylvestris. Deet was reported effective against the test species for at least 2 days after treatment when applied to boots (6 milliliters) and anklets (4 milliliters). Four milliters of Deet applied to the forearms, lower portion of the legs, neck and face of test subjects provided protection against the leech for at least 8 hours after treatment.

In tests conducted with aquatic leeches, Hirudo spp., Deet efficacy was marginal. Laboratory trials conducted with a 33% active ingredient preparation produced 30 minutes repellency. Field trials with the same formulation, however, provided only 12 minutes of protection. Additional field trials conducted with 45-50% Deet in varying inert formulations yielded protection times ranging from 1 to 50 minutes (Keegan et al. 1964, MRID 05002310). In a separate study, Keegan and Weaver (Keegan and Weaver 1964, MRID 00001035) evaluated 75% lotions and pressurized sprays containing 12.75% of Deet active ingredient. A 50% reduction in the number of leeches on a test subject was observed after five minute exposure periods. Neither formulation remained effective for a second five minute period.

The data indicate that formulations containing at least 50% Deet active ingredient adequately repels terrestrial leeches. With respect to aquatic leeches, the data are inadequate to support label claims.

### h. Mosquitoes

#### (1) Laboratory Studies

Most of the laboratory studies reviewed evaluated the efficacy of Deet against Aedes aegypti using the "first confirmed bite" method. Formulations ranging from 6.25 to 100% active ingredient of Deet afforded protection for periods from 2 to 14 hours. The wide variation in response resulted from a variety of factors. These factors may have included subject susceptibility, individual differences in laboratory-reared populations, time of day of the test, and other undescribed environmental conditions. The data further indicate that Deet can provide at least 3 hours of protection against mosquitoes following direct skin applications of formulations containing 10% or greater of the single active ingredient. Laboratory tests conducted to determine the minimum effective dose indicate that at least 0.02 to 0.20 milligram of Deet per square centimeter of skin must be applied to protect the forearms of human subjects exposed to caged A. aegypti.

#### (2) Field Studies

Numerous studies have been conducted to evaluate the effectiveness of Deet against mosquitoes. The data demonstrate that Deet is effective in repelling a wide spectrum of mosquito species, i.e., Aedes, Culex, Mansonia, Anopheles, and Psorophora. The protection times afforded by various dose levels ranged from 1 to 24 hours. Following exposure to 100% active ingredient Deet, maximum protection times of 20 hours were obtained against Culex pipiens and mixed populations comprised primarily of *Aedes* and *Mansonia* species. Formulations ranging from 10 to 50% afforded adequate protection from both *Aedes* and *Culex* mosquitoes.

Both the field and laboratory data currently available clearly indicate that Deet is effective in repelling mosquitoes.

### i. Stableflies

A relatively large number of papers dealing with Deet efficacy against the stablefly (*Stomoxys calcitrans*) are available. They provided a clear indication that Deet is effective in protecting human subjects from stablefly biting. A distinct dose/response relationship exists. The minimum protection time afforded a human test subject was 2.7 hours (S.C. Johnson and Son, Inc. 1974, MRID 00001095). This protection time resulted from a 1 gram per 645 $cm^2$ application of a 10% single active Deet formulation, the lowest percent active ingredient formulation for which data appear available. The maximum protection time indicated by the data was 8 hours, afforded by a 25% Deet active ingredient and ethanol formulation (Gilbert *et al*. 1957, MRID 05000236). Although formulation strengths up to 50% have been tested, the 8 hour duration reported by Gilbert was the maximum recorded for all studies. It can not be inferred, however, that 25% is the optimum Deet concentration for protection against stableflies, since other factors (wind, precipitation, etc.) also affect the product's effectiveness.

The data currently available clearly indicate that Deet is effective in repelling stableflies.

### j. Ticks

Wide variations in response levels have been noted in data on Deet applied to ticks. The variation appears relative to species, sex and life stage (Simironva and Dremova 1971, MRID 05002661) (Novak 1973, MRID 05000290). Even in studies conducted on the same subjects, considerable variation in test results are reported. In studies involving the Lone Star Tick, *Amblyomma americanum*, Gilbert (Gilbert 1957, MRID 0500237) reported marginal repellency when Deet was applied to cloth test surfaces at the rate of 2 grams active ingredient per square foot. Eight hour repellency was recorded at 52% active ingredient. In a field study; however, Gerberg (Gerberg 1966, MRID 00001171) reported adequate repellency for 7 hours utilizing the same 2 gram active ingredient per square foot application rate. Similarly, studies conducted on the Brown Dog Tick, *Rhiphicephalus sanguineus*, provided divergent results. In laboratory trials, Deet-treated cardboard (70% m-isomer at 5 milliters per square inches) yielded virtually no repellent activity (Kochhar 1974, MRID 05000150). A 25% Deet cream formulation, however, provided 21 to 47 hours of protection when applied at a rate of 0.018 - 0.028 milligrams per $cm^2$ to the shaved back of rabbits.

Although the Agency has reviewed papers dealing with a wide range of tick species, most available data are from foreign sources and involve species not found in the United States.

Among the species of concern to the Agency, *Demacentor andersoni, D. variabilis, Ixodes scapularis*, and *I. pacificus* do not appear within the literature. Given the absence of data relating to the majority of the tick species and the inconclusive nature of the overall data base, claims for tick repellency are not adequately substantiated. Claims for ticks, therefore, are not supported by this Standard. Any registrant desiring to retain or add claims for ticks must submit the appropriate efficacy data.

## C. Data Gaps

### 1. Use Sites

Registrants desiring to make claims of Deet efficacy for outdoor mist application will be required to submit supporting data.

### 2. Target Pests

#### a. Ceratopogonidae

The Agency will require formulation-specific data in each instance where a specific duration claim is requested.

#### b. Fleas

The Agency will require formulation-specific data in each instance where a specific duration claim is requested.

#### c. Chiggers

Virtually no data are available related to formulated products. Rather than require formulation-specific data for repellancy, at the time of product reregistration, registrants claiming on the label, "kills chiggers", must submit the calculations that demonstrate that the product will satisfactorily deposit a minimum of 1 gram of Deet active ingredient per square foot of treated cloth, when used in accordance with label directors. Since the Agency will not prescribe acceptable duration claims, whenever a claim of product duration is requested, formulation-specific data must be developed and submitted for Agency evaluation.

#### d. Leeches

Registrants desiring claims for aquatic leeches will be required to submit data derived from testing of the specific formulation proposed for (re)registration.

#### e. Mosquitoes

Registrants desiring duration claims of more than two hours will be required to submit formulation specific data.

#### f. Stableflies

Deet products, of any formulation type and containing 10% or more active ingredient, may bear claims for stablefly repellency. Sufficient data are available to allow for a general, limited duration claim. Utilizing the previous logic for mosquitoes, products containing 10% or greater concentration of Deet active ingredient may claim "repels stableflies for up to two hours." Registrant who wish to put this claim on their labels must also include a brief statement to the effect that the duration of protection may vary with the individual and that re-application may be required. Registrants desiring duration claims for periods longer that two hours will be required to submit formulation-specific data.

## D. Labeling

### 1. Use Sites

#### a. Human Skin, Clothing, Tents and Bedrolls

Claims may be made for biting flies, chiggers, deer flies, mosquitoes, fleas and stableflies.

#### b. Treatment of Screens in Domestic Dwellings

Claims for screen application may only be made for mosquitoes, ceratopogonid species, and black flies.

### 2. Target Pests

#### a. Black flies

Data currently available clearly indicate that Deet is effective in repelling black flies. The data also indicate efficacy of various doses and formulations. The Agency, therefore, will set limits on product labels. The lower limit of formulations tested was 15%, so the Agency will not accept efficacy claims for products containing less than 15% Deet as the sole active ingredient. Because of the limits of the data reviewed, the Agency cannot prescribe claims of product duration for all formulations, strengths and types. The Agency will require formulation-specific data in cases where producers wish to make a claim.

#### b. Deerflies

Given the extreme variation in protection times for different species, the Agency will not accept duration claims for deerflies. Duration claims for deerfly protection, therefore, will be refused for Deet products. Deet formulations containing 10% or more active ingredient however, may bear a limited, general claim for deer fly repellency.

#### c. Leeches

Because there are no terrestrial leeches in the U.S., the Agency does not believe that the public interest would be served by permitting these claims on consumer product labeling. In the past, there have been occasions where these products were required for use by American military forces. The Agency is prepared to permit the labeling of products for terrestrial leeches with the qualification that all such products bear the statement "For Use in Tropical Areas Where Pest Occurs."

#### d. Mosquitoes

Deet products of any formulation or type, containing 10% or more active ingredient, may bear claims for mosquito repellency. With regard to duration claims, the Agency will not prescribe claims for all variations of formulation strengths and types. There do appear, however, sufficient data to allow for a general, limited duration claim. Products containing 10% or greater concentrations of Deet may claim "repels mosquitoes for up to two hours."

Registrants desiring to put this claim on their labels must also include a brief statement to the effect that the duration of protection may vary with the individual and that re-application maybe required.

## APPENDIX I

## SUPPORTING COMPANY EFFICACY DATA

| CITATION | Blackflies | Ceratopogonid species | Chiggers | Deerflies | Fleas | Houseflies | Leeches | Mosquitoes | Stableflies | Ticks |
|---|---|---|---|---|---|---|---|---|---|---|
| Allenbaugh<br>(1965)<br>00001003 | | | | X | X | | | X | X | X |
| Altman<br>(1969)<br>00001172 | | | | | | | | X | | |
| Eastman<br>(1969)<br>00001169 | X | | | X | | | | X | | |
| Gerberg<br>(1966)<br>00001171 | X | X | X | | X | | | X | | X |
| Gerberg<br>(1973)<br>00001065 | | | | | | | | X | | |
| Gertler et al.<br>(1962)<br>00001018 | | | X | | | | | X | | X |
| Gilbert et al.<br>(1957)<br>00001021 | | X | | X | | | | X | X | |
| Gilbert et al.<br>(1957)<br>00001022 | | | X | | X | | | X | | X |
| Gilbert et al.<br>(1965)<br>00001033 | | | | | | X | | | | |

## APPENDIX I

## SUPPORTING COMPANY EFFICACY DATA

| CITATION | Blackflies | Ceratopogonid species | Chiggers | Deerflies | Fleas | Houseflies | Leeches | Mosquitoes | Stableflies | Ticks |
|---|---|---|---|---|---|---|---|---|---|---|
| Gilbert et.al.<br>(1970)<br>00001162 | | | | | | | | X | | |
| Gilbert et.al.<br>(1970)<br>00001167 | | | | | | | | X | X | |
| Gouck et.al.<br>(1967)<br>00001032 | | | | | | | X | | | |
| Granett<br>(1969)<br>00001109 | | | | X | | | | X | X | |
| Granett et.al.<br>(1971)<br>00001138 | X | | | | | | | X | | |
| Granett et.al.<br>(1973)<br>00001137 | X | | | | | | | | | |
| Granett et.al.<br>(1973)<br>00001127 | X | | | | | | | | | |
| Grothaus et.al<br>(1975)<br>00001038 | X | X | | X | | | | X | | |
| Haynes<br>(1969)<br>00004864 | | | | X | | | | X | X | |

## APPENDIX I

## SUPPORTING COMPANY EFFICACY DATA

| CITATION | Blackflies | Ceratopogonid species | Chiggers | Deerflies | Fleas | Houseflies | Leeches | Mosquitoes | Stableflies | Ticks |
|---|---|---|---|---|---|---|---|---|---|---|
| Hercules<br>(1977)<br>00001068 |  | X |  | X |  |  |  | X | X |  |
| Hercules<br>(1957)<br>00001025 |  | X |  | X |  |  |  | X | X |  |
| Hercules<br>(1961)<br>00001105 |  | X |  | X |  |  |  | X | X |  |
| Keegan et.al.<br>(1964)<br>00001034 |  |  |  |  |  |  | X |  |  |  |
| Keegan et.al.<br>(1964)<br>00001035 |  |  |  |  |  |  | X |  |  |  |
| Khan et.al.<br>(1972)<br>00001163 |  |  |  |  |  |  |  | X |  |  |
| Lahr<br>(1970)<br>00001108 |  |  |  |  |  |  |  | X |  |  |
| Lahr<br>(1970)<br>00004868 |  |  |  |  |  |  |  | X | X |  |
| Lahr<br>(1970)<br>00004869 |  |  |  |  |  |  |  | X |  |  |

## APPENDIX I

## SUPPORTING COMPANY EFFICACY DATA

| CITATION | Blackflies | Ceratopognoid species | Chiggers | Deerflies | Fleas | Houseflies | Leeches | Mosquitoes | Stableflies | Ticks |
|---|---|---|---|---|---|---|---|---|---|---|
| Lahr<br>(1970)<br>00004870 | | | | | | | | X | | |
| Lahr<br>(1972)<br>00001124 | X | | | X | | | | X | X | |
| Lomax<br>(1968)<br>00001110 | X | X | | X | | | | X | X | |
| Lomax<br>(1968)<br>00004865 | X | X | | X | | | | X | X | |
| Lomax<br>(1969)<br>00001118 | X | X | | X | | | | X | X | |
| Lomax<br>(1970)<br>00001115 | | | | | | | | X | X | |
| Lomax<br>(1970)<br>00001117 | | | | | | | | X | X | |
| Mace<br>(1966)<br>00001084 | | | | | | | | X | | |
| McAndless<br>(1974)<br>00001037 | | | | X | | | | X | | |

## APPENDIX I

## SUPPORTING COMPANY EFFICACY DATA

| CITATION | Blackflies | Ceratopogonid species | Chiggers | Deerflies | Fleas | Houseflies | Leeches | Mosquitoes | Stableflies | Ticks |
|---|---|---|---|---|---|---|---|---|---|---|
| MGK Co.<br>(1957)<br>00001055 | | X | X | X | X | | | X | X | X |
| MGK Co.<br>(1974)<br>00001053 | | | | | | | | X | | |
| Miller<br>(1955)<br>00001000 | | | | | | | | | X | |
| Mitchell<br>(1971)<br>00001129 | | | | | | X | | | | |
| Neumiller<br>(1972)<br>00001072 | | | | | | | | X | X | |
| Pierce<br>(1958)<br>00001104 | | | X | | | | | X | X | |
| S.C.Johnson<br>(1964)<br>00001168 | | | | | | | | X | X | |
| S.C.Johnson<br>(1969)<br>00001170 | | | | | | | | X | X | |
| S.C.Johnson<br>(1974)<br>00001095 | X | | | X | | | | X | X | |

# APPENDIX I

## SUPPORTING COMPANY EFFICACY DATA

| CITATION | Blackflies | Ceratopogonid species | Chiggers | Deerflies | Fleas | Houseflies | Leeches | Mosquitoes | Stableflies | Ticks |
|---|---|---|---|---|---|---|---|---|---|---|
| S.C.Johnson<br>(1974)<br>00001097 | | | | | | | | X | X | |
| S.C.Johnson<br>(1977)<br>00001103 | X | X | | X | | | | X | X | |
| Schley et.al.<br>(1974)<br>00001052 | | | | | | | | X | | |
| Smith<br>(1957)<br>00001113 | | | X | | X | | | X | | X |
| Smith<br>(1970)<br>00001166 | | | | | | | | X | | |
| Smith et.al.<br>(1957)<br>00001010 | | | | | | | | X | | |
| Smith et.al.<br>(1959)<br>00001164 | | | X | | | | | X | | X |
| Smith et.al.<br>(1961)<br>00001184 | | | | | | | | X | | |
| Union Carbide<br>(1970)<br>00001116 | | | | | | | | X | X | |

## APPENDIX I

## SUPPORTING COMPANY EFFICACY DATA

| CITATION | Blackflies | Ceratopogonid species | Chiggers | Deerflies | Fleas | Houseflies | Leeches | Mosquitoes | Stableflies | Ticks |
|---|---|---|---|---|---|---|---|---|---|---|
| Union Carbide<br>(1970)<br>00001107 |  | X |  | X |  |  |  | X | X |  |
| Union Carbide<br>(1970)<br>00001111 | X | X |  | X |  |  |  | X | X |  |
| Union Carbide<br>(1971)<br>00001177 |  | X |  | X |  |  |  | X | X |  |
| U.S.D.A.<br>(1959)<br>00001165 |  |  | X |  |  |  |  | X |  | X |
| WARF<br>(1960)<br>000010040 |  |  |  |  |  |  |  | X |  |  |
| WARF<br>(1960)<br>00001041 |  |  |  |  |  |  |  | X | X |  |
| WARF<br>(1963)<br>00001030 |  |  |  |  |  | X |  | X |  |  |
| WARF<br>(1964)<br>00001046 |  |  |  |  |  |  |  |  | X |  |
| WARF<br>(1964)<br>00001047 |  |  |  |  |  |  |  | X |  |  |

## VIII. CASE BIBLIOGRAPHY

### Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into 3 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard; (2) citations examined and judged to be inappropriate for use in developing the standard; and (3) standard reference material. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix wihich shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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Section II

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## Section III

## OFFICE OF PESTICIDE PROGRAMS
## REGISTRATION STANDARD BIBIOGRAPHY
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